IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

BARBARA THOMPSON, KIMBERLY WILLIAMS, KELSIE SPEARS, and LAURA PITLIK,	)	
Plaintiffs,	)	Civil Action No. _____
V.	)	
FEEL TECH CO., LTD.; DBM CORPORATION USA (f/k/a BENEV DBM CORPORATION, f/k/a DBM CORPORATION, INC.); BENEV COMPANY INC.; and AESTHETICS DISTRIBUTION, LLC, d/b/a AESTHETICS DISTRIBUTIONS,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Plaintiffs BARBARA THOMPSON, KIMBERLY WILLIAMS, KELSIE SPEARS, and LAURA PITLIK (collectively, "Plaintiffs"), complaining of Defendants FEEL TECH CO., LTD., DBM CORPORATION USA (f/k/a BENEV DBM Corporation, DBM Corporation Inc.), BENEV COMPANY INC., and AESTHETICS DISTRIBUTION, LLC, d/b/a AESTHETICS DISTRIBUTIONS and for cause of action would respectfully show the Court the following:

I. PRELIMINARY STATEMENT

1.0 This is a product liability action arising from the marketing, importation, distribution, and sale of a medical device — the Miracu PDO Mono Thread — that was not cleared

by the United States Food and Drug Administration for the cosmetic facial procedures for which it was marketed, promoted, and sold. Between April 16 and April 23, 2024, four women underwent PDO thread placement procedures at a Dallas, Texas cosmetic aesthetic facility using Miracu Mono Thread, Model No. 29036B, Lot 533B1B. Each developed a severe, treatment-resistant Mycobacterium abscessus infection at the thread insertion sites — a cluster of antibiotic-resistant bacterial infections that resulted in surgical drainage of facial abscesses, PICC line placement, prolonged intravenous antibiotic therapy, and permanent facial scarring.

1.1 At the time the product was manufactured, imported, distributed, and used, no FDA 510(k) clearance existed for the Miracu Mono Thread as a distinct device type. The only clearance in existence — K172602, granted November 14, 2018 — covered only the Miracu barbed surgical suture and expressly stated the product is "not intended for lifting and supporting tissues." A separate clearance for the Mono Thread, K251414, was not applied for until May 7, 2025 --- more than thirteen months after Plaintiffs were injured --- and was not granted until October 20, 2025. That clearance, like K172602 before it, expressly states the product 'is not intended for lifting and supporting tissues' --- meaning that the cosmetic facial enhancement procedures for which Defendants marketed the product were outside the cleared indications of every applicable FDA clearance, both at the time of use and under the clearance eventually obtained. That clearance, too, states the product "is not intended for lifting and supporting tissues." Every Defendant, nonetheless, marketed, distributed, and sold the Miracu Mono Thread for cosmetic facial tissue enhancement and tightening --- a use expressly excluded from every applicable FDA clearance regardless of when that clearance was obtained.

1.2 Plaintiffs bring this action against the manufacturer of the defective product, the exclusive United States distributor that imported and commercially promoted it in knowing

disregard of its regulatory status, the corporate co-venturer that participated in that distribution enterprise, and the regional distributor that sold the specific defective product to the Dallas medical spa where Plaintiffs were treated. Plaintiffs seek compensatory and exemplary damages for the permanent physical injuries and disfigurement they suffered as a direct result of Defendants' conduct.

II. PARTIES

A. Plaintiffs

2.0 Plaintiff BARBARA THOMPSON is a natural person and citizen of the State of Oklahoma, currently domiciled in Bryan County, Oklahoma. She underwent a PDO Mono Thread procedure at Face Studio Wow, 1800 N. Haskell Avenue, Suite 200, Dallas, Texas 75204, on April 23, 2024, using Miracu PDO Mono Thread, Model No. 29036B, Lot 533B1B. She suffered the injuries described herein as a direct result of that procedure.

2.1 Plaintiff KIMBERLY WILLIAMS is a natural person and citizen of the State of Texas, currently domiciled in Collin County, Texas. She underwent a PDO Mono Thread procedure at Face Studio Wow, 1800 N. Haskell Avenue, Suite 200, Dallas, Texas 75204, on April 17, 2024, using Miracu PDO Mono Thread, Model No. 29036B, Lot 533B1B. She suffered the injuries described herein as a direct result of that procedure.

2.2 Plaintiff KELSIE SPEARS is a natural person and citizen of the State of Texas, currently domiciled in Dallas County, Texas. She underwent a PDO Mono Thread procedure at Face Studio Wow, 1800 N. Haskell Avenue, Suite 200, Dallas, Texas 75204, on April 17, 2024, using Miracu PDO Mono Thread, Model No. 29036B, Lot 533B1B. She suffered the injuries described herein as a direct result of that procedure.

2.3 Plaintiff LAURA PITLIK is a natural person and citizen of the State of Texas, currently domiciled in Dallas County, Texas. She underwent a PDO Mono Thread procedure at Face Studio Wow, 1800 N. Haskell Avenue, Suite 200, Dallas, Texas 75204, on April 16, 2024, using Miracu PDO Mono Thread, Model No. 29036B, Lot 533B1B. She suffered the injuries described herein as a direct result of that procedure.

B. Defendants

2.4 Defendant FEEL TECH CO., LTD. ("Feel Tech") is a corporation organized and existing under the laws of the Republic of Korea, with its registered office located at #313, Woorim W-city, 9-22, Pangyo-ro, 255Beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea, and its principal manufacturing facility located at 3-4 Floor, Standard Factory 2-dong, 15, Jayumuyeok 2-gil, Gunsan-si, Jeollabuk-do, Korea. Feel Tech is a citizen or subject of the Republic of Korea within the meaning of 28 U.S.C. § 1332(a)(2). Feel Tech is the manufacturer of record for the Miracu PDO Mono Thread product at issue on all FDA filings and product packaging. Feel Tech may be served pursuant to Fed. R. Civ. P. 4(f)(1) and the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, 20 U.S.T. 361, T.I.A.S. No. 6638, through South Korea's Central Authority: Director of International Affairs, National Court Administration, Supreme Court of Korea, Seocho-daero 219, Seocho-gu, Seoul 06590, Republic of Korea.

2.5 Defendant DBM CORPORATION USA (formerly known as BENEV DBM Corporation and DBM Corporation, Inc.) ("DBM") is a corporation organized and existing under the laws of the State of California, Entity No. 3817917, with its principal place of business at 23263 Madero, Suite B, Mission Viejo, California 92691. DBM is a citizen of the State of California for purposes of 28 U.S.C. § 1332(c)(1). DBM was incorporated on August 18, 2015, as

BENEV DBM Corporation and changed its name to DBM Corporation USA by Certificate of Amendment filed with the California Secretary of State on August 5, 2025. At all times relevant to this action, DBM (then operating as BENEV DBM Corporation) was the exclusive U.S., Mexican, and Canadian distributor of Miracu PDO Threads and held itself out as the exclusive representative of the Miracu product line in the United States. DBM imported, distributed, marketed, promoted, and sold the defective Miracu PDO Mono Thread that is the subject of this lawsuit. DBM may be served through its registered agent for service of process, Gihyun Kim, at 23263 Madero, Suite B, Mission Viejo, California 92691, or through any officer, director, managing agent, or general agent as permitted by Fed. R. Civ. P. 4(h)(1).

2.6 Defendant BENEV COMPANY INC. ("BENEV") is a corporation organized and existing under the laws of the State of California, Entity No. 2186210, with its principal place of business at 23263 Madero, Suite A, Mission Viejo, California 92691. BENEV is a citizen of the State of California for purposes of 28 U.S.C. § 1332(c)(1). BENEV is a U.S. FDA-registered pharmaceutical, cosmeceutical, and medical device company (FEI No. 3003205477). BENEV is a co-venturer with DongBang Medical Co., Ltd. in the formation and operation of DBM, through which the Miracu PDO Thread product was distributed in the United States. BENEV shares the same physical address and overlapping officers and directors with DBM at all times relevant to this action, participated in the marketing, promotion, distribution, and sale of the Miracu product in the United States, and is an integral part of the single enterprise through which the product reached the Texas market. BENEV may be served through its registered agent for service of process, Kyungmin Park, at 23263 Madero, Suite A, Mission Viejo, California 92691, or through any officer, director, managing agent, or general agent as permitted by Fed. R. Civ. P. 4(h)(1).

2.7 Defendant AESTHETICS DISTRIBUTION, LLC, d/b/a AESTHETICS DISTRIBUTIONS ("Aesthetics"), is a limited liability company organized and existing under the laws of the State of Florida, with its principal place of business at 20400 Trailside Drive, Estero, Florida 33928. For purposes of diversity jurisdiction, the citizenship of Aesthetics is determined by the citizenship of each of its members. On information and reasonable belief, no member of Aesthetics Distribution, LLC is a citizen of the State of Texas and that complete diversity therefore exists. Aesthetics operates as a Group Purchasing Organization ("GPO") that markets, promotes, distributes, and sells medical aesthetic products — including the Miracu PDO Mono Thread — to its medical provider member accounts in Texas and throughout the United States. Aesthetics engages in business in Texas but has not designated or maintained a registered agent for service of process in Texas. Aesthetics may be served through its registered agent in Florida, Ken Sutherland Manager & Registered Agent 12831 Carrington Circle #202, Naples, FL 34105 or by serving any member or manager of the company, or pursuant to Fed. R. Civ. P. 4(h)(1) in any manner permitted by Florida law.

III. SUBJECT MATTER JURISDICTION

3.0 This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). Complete diversity of citizenship exists between Plaintiffs and all Defendants, and the amount in controversy exceeds $75,000 as to each Plaintiff, exclusive of interest and costs.

3.1 Plaintiffs Barbara Thompson (Oklahoma), Kimberly Williams (Texas), Kelsie Spears (Texas), and Laura Pitlik (Texas) are citizens of states other than the states of which any Defendant is a citizen. Defendant DBM Corporation USA is a citizen of California. Defendant BENEV Company Inc. is a citizen of California. Defendant Aesthetics Distribution, LLC's citizenship of Florida. Defendant Feel Tech Co., Ltd. is a citizen or subject of the Republic of

Korea, a foreign state. No Plaintiff shares state citizenship with any Defendant. Complete diversity therefore exists under 28 U.S.C. § 1332(a)(1) and (2).

3.2 The amount in controversy exceeds $75,000, exclusive of interest and costs, as to each Plaintiff individually. Each Plaintiff suffered permanent facial disfigurement and scarring, required surgical drainage procedures, PICC line placement, and prolonged courses of intravenous antibiotic therapy for treatment-resistant Mycobacterium abscessus infection. Each Plaintiff seeks, among other things, compensation for permanent physical impairment and disfigurement, past and future medical expenses, past and future physical pain and mental anguish, lost wages and loss of earning capacity, and exemplary damages.

IV. VENUE

4.0 Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claims asserted herein occurred in the Northern District of Texas, Dallas Division. Specifically: (a) each Plaintiff's PDO Mono Thread procedure was performed at Face Studio Wow, 1800 N. Haskell Avenue, Suite 200, Dallas, Texas 75204, a location within this District; (b) the defective Miracu Mono Thread product was delivered to, used at, and caused injury in this District; (c) each Plaintiff's Mycobacterium abscessus infection manifested, progressed, and was medically treated in this District; (d) each Plaintiff sustained physical injuries, including facial abscess formation, scarring, and disfigurement, in this District; and (e) Plaintiffs' past and ongoing damages, including medical expenses, physical pain, and mental anguish, arise from injuries sustained in this District.

4.1 Venue is independently proper as to Defendant Feel Tech Co., Ltd. under 28 U.S.C. § 1391(c)(3), because Feel Tech is not a resident of the United States and may be sued in any judicial district. Feel Tech's joinder is disregarded in determining where this action may be brought

with respect to the other Defendants.

V. PERSONAL JURISDICTION

A. Personal Jurisdiction Over Defendant Feel Tech Co., Ltd.

5.0 This Court has personal jurisdiction over Feel Tech Co., Ltd. pursuant to Fed. R. Civ. P. 4(k)(2). Plaintiffs are unaware of any state in which Feel Tech is subject to the courts of general jurisdiction at the time this Complaint is filed. Feel Tech has established sufficient minimum contacts with the United States as a whole to satisfy the constitutional requirements of due process, and the exercise of jurisdiction over Feel Tech is reasonable and fair.

5.1 Feel Tech's contacts with the United States that give rise to jurisdiction under Rule 4(k)(2) include, without limitation, the following:

a) Feel Tech submitted and obtained FDA 510(k) clearance K172602 on November 14, 2018, actively seeking authorization from the United States Food and Drug Administration to market its products for sale within the United States. This regulatory submission reflects a purposeful act directed at the U.S. market and the U.S. federal regulatory system.

b) Feel Tech submitted a second FDA 510(k) application, K251414, on May 7, 2025, and received clearance on October 20, 2025, demonstrating an ongoing and intentional relationship with U.S. regulatory authorities that spans years and multiple regulatory engagements.

c) Feel Tech maintains a United States regulatory representative, Albert Rego, Ph.D., located at 25401 Cabot Road, #122, Laguna Hills, California 92653, who serves as Feel Tech's designated U.S. agent for FDA regulatory communications and correspondence. The maintenance of a U.S.-based regulatory representative constitutes continuous and systematic contact with the United States.

d) Feel Tech entered into a commercial joint venture arrangement with DongBang

Medical Co., Ltd. and BENEV Company Inc. specifically for the purpose of distributing Miracu PDO Thread products throughout the United States, Canada, and Mexico through DBM Corporation USA as the exclusive North American distributor. Feel Tech knowingly and deliberately established a U.S. distribution enterprise to penetrate and exploit the U.S. medical aesthetic market.

e) Feel Tech manufactured, packaged, and exported the Miracu PDO Mono Thread product — including the specific product at issue, Model No. 29036B, Lot 533B1B — to the United States for commercial distribution and sale. The flow of this product from Feel Tech's Korean manufacturing facility through DBM's U.S. distribution network to healthcare providers throughout the United States, including Dallas, Texas, reflects a deliberate and sustained commercial relationship with the U.S. market.

f) The claims asserted herein arise directly from and relate to Feel Tech's U.S.-directed contacts: its FDA submissions established the regulatory framework (and its deficiencies) governing the product's legality; its U.S. distribution network placed the specific product at issue into the hands of a Texas healthcare provider; and its manufacturing and design decisions affected the specific product that injured Plaintiffs in the Northern District of Texas.

5.2 The exercise of personal jurisdiction over Feel Tech in this Court is consistent with the constitutional requirements of due process. Feel Tech purposefully availed itself of the U.S. market through sustained commercial conduct spanning years, multiple regulatory engagements, a designated U.S. regulatory agent, and a U.S. distribution enterprise specifically designed to place its products into the U.S. stream of commerce for use on U.S. patients. This case arises directly from that U.S.-directed activity. Exercising jurisdiction is fair and reasonable: the forum has a compelling interest in protecting its residents from defective medical devices distributed and used

within its borders; Plaintiffs would face an insurmountable burden litigating in Korea; the United States has a strong policy interest in enforcing its medical device laws; and consolidated litigation in a single forum serves judicial economy.

B. Personal Jurisdiction Over Defendants DBM Corporation USA and BENEV Company Inc.

5.3 This Court has specific personal jurisdiction over Defendants DBM Corporation USA and BENEV Company Inc. pursuant to Fed. R. Civ. P. 4(k)(1)(A) and the Texas long-arm statute, Tex. Civ. Prac. & Rem. Code § 17.042. Each of these Defendants purposefully directed commercial activities at the State of Texas, and Plaintiffs' claims arise directly out of and relate to those Texas-directed activities.

5.4 DBM and BENEV's contacts with Texas that give rise to specific jurisdiction include, without limitation, the following:

a) DBM, as the exclusive U.S. distributor of Miracu PDO Threads, marketed, promoted, distributed, and sold the Miracu product to healthcare practitioners and aesthetic facilities throughout the United States, including within the State of Texas, as part of its ongoing commercial distribution enterprise targeting the U.S. medical aesthetic market.

b) At all times relevant to this action, Defendant Dr. Dee Martinez, a Dallas, Texas-licensed physician who served as the medical director of Face Studio Wow in Dallas, was registered within DBM's and/or BENEV's authorized provider network or distributor system. DBM and/or BENEV knowingly maintained a relationship with Dr. Martinez as part of their Texas market penetration strategy, reflecting a deliberate and intentional targeting of the Texas healthcare market.

c) DBM and/or BENEV partnered with and solicited Texas-based physicians and Texas-based aesthetic providers for advertising, promotional, and marketing purposes as part of

their Texas-directed commercial strategy.

d) DBM directed the specific product at issue — Miracu PDO Mono Thread, Model No. 29036B, Lot 533B1B — into the Texas stream of commerce through its authorized U.S. distribution chain, with actual knowledge that the product would be purchased by and used on Texas patients. The product reached Face Studio Wow in Dallas, Texas, through that distribution chain.

e) BENEV Company Inc. co-operated the U.S. distribution enterprise with DBM, sharing the same physical address, officers, and directors, and participated in the marketing, promotion, and sale of the Miracu product in the United States, including Texas. BENEV's FDA establishment registration (FEI No. 3003205477) reflects its active participation in the U.S. regulatory framework governing the product's domestic distribution.

f) Following each Plaintiff's PDO thread procedure, adverse event reports were filed under the DBM/BENEV corporate name identifying Texas patients, including Plaintiffs, as having suffered injuries from the Miracu product distributed by these Defendants. DBM and BENEV therefore had actual, contemporaneous knowledge of injuries to Texas patients arising from their Texas-directed distribution activities.

g) DBM and BENEV operated websites — including www.MIRACUUSA.com and www.dbmcorpusa.com — through which they marketed the Miracu product to U.S. healthcare providers, including Texas providers, and through which practitioners, including those in Texas, could locate and purchase the product.

5.5 Plaintiffs' claims arise directly out of and relate to DBM's and BENEV's Texas-directed contacts. The specific product that injured Plaintiffs was placed into the Texas market through DBM's and BENEV's distribution enterprise; the injuries were suffered by Texas patients

at a Texas facility; and the claims of Plaintiffs Williams, Spears, and Pitlik — Texas residents injured in Texas — arise directly from DBM's and BENEV's deliberate targeting of the Texas medical aesthetic market. The claims of Plaintiff Thompson arise from the same commercial activity that placed the identical product lot into the hands of the same Texas practitioner.

5.6 The exercise of personal jurisdiction over DBM and BENEV in this Court is consistent with traditional notions of fair play and substantial justice. Both entities are California corporations with substantial resources that have deliberately engaged the U.S. medical device market on a national scale. This District provides the most convenient and appropriate forum, as the injuries occurred here, the evidence is located here, and the Texas Plaintiffs (three of the four) reside here.

C. Personal Jurisdiction Over Defendant Aesthetics Distribution, LLC

5.7 This Court has specific personal jurisdiction over Defendant Aesthetics Distribution, LLC pursuant to Fed. R. Civ. P. 4(k)(1)(A) and the Texas long-arm statute, Tex. Civ. Prac. & Rem. Code § 17.042. Aesthetics purposefully directed commercial activities at the State of Texas, and Plaintiffs' claims arise directly from and relate to those Texas-directed activities.

5.8 Aesthetics Distribution, LLC's contacts with Texas that give rise to specific jurisdiction include, without limitation, the following:

a) Aesthetics, operating as a Group Purchasing Organization, solicited and enrolled Texas healthcare providers as member accounts and marketed, promoted, and sold medical aesthetic products — including the Miracu PDO Mono Thread — to its Texas member accounts as a regular and ongoing course of commercial activity.

b) On information and belief, Aesthetics sold and shipped the specific Miracu PDO Mono Thread product at issue — or the pouch from which Model No. 29036B, Lot 533B1B was

drawn — directly to Face Studio Wow, LLC and/or Dr. Dee Martinez in Dallas, Texas. If confirmed by discovery, this direct commercial transaction with a Texas buyer constitutes the clearest possible basis for specific jurisdiction: a deliberate sale of the defective product to a Texas customer, used on Texas patients, causing injury in Texas.

c) Aesthetics engaged in the business of distributing products within the State of Texas as a regular and anticipated course of commercial activity, as evidenced by its conduct of business in Texas without designating or maintaining a registered agent for service of process in Texas in compliance with Texas law — a circumstance that itself confirms Aesthetics' ongoing business activities in the state.

d) Aesthetics' claims arise directly from its Texas-directed commercial activity: the sale of the defective product to a Texas buyer, the use of that product on Texas patients in a Texas facility, and the resulting injuries to Texas residents.

5.9 The exercise of personal jurisdiction over Aesthetics in this Court comports with traditional notions of fair play and substantial justice. Aesthetics purposefully transacted business in Texas as part of its national GPO distribution model, has practical and logistical resources commensurate with operating a national distribution enterprise, and the forum has a compelling interest in providing redress to Texas plaintiffs injured by products sold into Texas by Aesthetics.

VI. FACTUAL BACKGROUND

A. The Miracu PDO Mono Thread: Product Identification

6.0 The product at issue is the Miracu PDO Mono Thread, Model No. 29036B, Size 29GX30mm, Lot 533B1B, manufactured on December 13, 2023, with an expiration date of December 12, 2025 (hereinafter the "Miracu Mono Thread" or the "Product"). The Product consists of smooth, non-barbed polydioxanone (PDO) monofilament sutures attached to insertion

needles, packaged in a 25-count sterile pouch and designated as a single-use medical device.

6.1 The Miracu Mono Thread is classified as a medical device under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h), because it is an apparatus intended for use in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body. As a medical device, it was required to have valid FDA 510(k) clearance before being introduced into interstate commerce for sale or use in the United States. 21 U.S.C. § 360(k); 21 C.F.R. § 807.81(a)(3).

B. The Manufacturer: Feel Tech Co., Ltd.

6.2 Defendant Feel Tech Co., Ltd. is the manufacturer of record for the Miracu PDO Mono Thread on all FDA filings and product packaging. Feel Tech designed, produced, assembled, and packaged the Miracu Mono Thread at its manufacturing facility in Gunsan-si, Jeollabuk-do, Korea, and placed the product into the stream of commerce for distribution and sale in the United States through DBM Corporation USA as its exclusive North American distributor.

6.3 Feel Tech is affiliated with and/or operates in conjunction with DongBang Medical Co., Ltd., a Korean entity based in Seongnam-si, Gyeonggi-do, Korea. Feel Tech uses DongBang Medical's email domain for FDA regulatory correspondence, and DongBang Medical has publicly identified BENEV DBM Corporation as a U.S. business partner. The two entities share overlapping business addresses and, on information and reasonable belief, operate as affiliated entities in the manufacture and distribution of the Miracu product line.

C. The Distributor Defendants

6.4 Defendant DBM Corporation USA was incorporated as BENEV DBM Corporation on August 18, 2015, as a joint venture between Defendant BENEV Company Inc. and DongBang Medical Co., Ltd., specifically for the purpose of distributing Miracu PDO Thread products in the

United States, Canada, and Mexico. DBM operated under the name BENEV DBM Corporation throughout the period relevant to this action and changed its name to DBM Corporation USA by Certificate of Amendment dated August 5, 2025. DBM was the official, exclusive U.S. distributor of Miracu PDO Threads and operated the distribution websites www.MIRACUUSA.com and www.dbmcorpusa.com. DBM announced FDA 510(k) clearance for Miracu on December 11, 2018, claiming — inaccurately with respect to the Mono Thread product at issue — that it was "the first PDO thread to receive 510(k) clearance in the U.S. market." Adverse event reports filed following Plaintiffs' injuries bore the name DBM Corporation identifying Texas patients, including Plaintiffs, as having suffered injuries from the Miracu product distributed by these Defendants.[1]

6.5 Defendant BENEV Company Inc. is a U.S. FDA-registered pharmaceutical, cosmeceutical, and medical device company and is the BENEV joint venture partner in DBM Corporation USA. BENEV shared the same physical address, officers, and directors with DBM at all relevant times. BENEV participated in the marketing, promotion, and distribution of the Miracu product in the United States and co-operated the U.S. distribution enterprise through which the product was sold. BENEV had full awareness of the product's regulatory status, distribution practices, and marketing representations at all relevant times.

6.6 Defendant Aesthetics Distribution, LLC is a Group Purchasing Organization that enrolled healthcare provider "member" accounts and marketed, promoted, distributed, and sold medical aesthetic products — including the Miracu PDO Mono Thread — to its members. On information and reasonable belief, Aesthetics distributed and/or sold the Miracu PDO Mono

[1] On information and belief, the adverse event reports submitted following Plaintiffs' injuries in July 2024 are not reflected in any publicly available FDA MAUDE database records for the product at issue. If confirmed, this absence raises questions regarding whether the reports were filed in compliance with 21 C.F.R. Part 803's mandatory reporting requirements and whether the FDA had complete safety information when processing the subsequently-filed 510(k) application K251414."

Thread product at issue to Face Studio Wow, LLC and/or Dr. Dee Martinez in Dallas, Texas, for use in the cosmetic procedures that injured Plaintiffs. Aesthetics had actual or constructive knowledge that it was distributing a product marketed for off-label cosmetic use that lacked valid FDA clearance for that use.

D. FDA Regulatory Status: No Valid Clearance for the Mono Thread

6.7 The only FDA 510(k) clearance in existence for any Miracu product at the time of the procedures in April 2024 was clearance K172602, granted November 14, 2018. K172602 covered only the Miracu barbed surgical suture — a device with bi-directional barbs along the suture monofilament intended for soft tissue approximation in dermatological applications. K172602 expressly states the cleared device is "not intended for lifting and supporting tissues." The Miracu Mono Thread — which has no barbs along the suture monofilament — is a distinct device from the barbed suture covered by K172602. The Mono Thread and the barbed suture differ in physical design, construction, mechanism of action, and intended function.

6.8 No separate FDA 510(k) clearance for the Miracu Mono Thread existed at the time the product was manufactured (December 2023), imported, distributed, or used on Plaintiffs (April 2024). The distribution and sale of the Miracu Mono Thread in the United States without a valid FDA 510(k) clearance for the non-barbed Mono Thread device type at the time of manufacture, importation, distribution, and use constituted a prohibited act under 21 U.S.C. § 331(a) and (k). This regulatory violation is significant not only as a per se violation, but because it means the product was never subjected to the FDA safety review that would have identified --- and required mitigation of --- the specific infection risks associated with cosmetic use of an implantable suture in non-surgical aesthetic settings. The absence of a valid clearance at the time of distribution and

use eliminates any compliance presumption that would otherwise exist under Tex. Civ. Prac. & Rem. Code § 82.008 and independently constitutes negligence per se.

6.9 Defendant Feel Tech did not apply for a separate 510(k) clearance for the Mono Thread until May 7, 2025 — more than thirteen months after Plaintiffs were injured. That clearance, K251414, was not granted until October 20, 2025 — more than eighteen months after the procedures at issue. Clearance K251414 contains the same express restriction as K172602: the Miracu Mono Thread, even when cleared, "is not intended for lifting and supporting tissues." The cosmetic facial enhancement and tissue tightening procedures documented in each Plaintiff's patient record --- and for which all Defendants marketed and sold the Miracu Mono Thread --- were therefore outside the cleared indications of every FDA clearance applicable to the Miracu product line. This is true of K172602 (the only clearance in existence in April 2024) and equally true of K251414 (the Mono-specific clearance obtained eighteen months after Plaintiffs were injured) --- both of which affirmatively state the product is not intended for tissue lifting and supporting. The eventual grant of K251414 did not retroactively authorize the use for which the product was marketed, and does not retroactively supply the safety warnings and sterile technique guidance whose absence caused Plaintiffs' injuries.

E. Defendants' Off-Label Marketing

6.10 Notwithstanding the foregoing, all Defendants marketed, promoted, distributed, and sold the Miracu Mono Thread for cosmetic facial enhancement and tissue tightening procedures in non-surgical aesthetic settings — including medspas, aesthetic clinics, and cosmetic studios — throughout the United States, including Texas. Defendants' marketing materials, product promotional literature, authorized distributor communications, and sales representations to healthcare practitioners — including, on information and belief, to the practitioners at Face

Studio Wow in Dallas, Texas — described and promoted the Miracu Mono Thread as a product suitable for cosmetic facial thread lifting and tissue tightening. DBM and BENEV's website www.MIRACUUSA.com promoted the Miracu product for cosmetic uses, and DBM publicly claimed that the product had FDA 510(k) clearance — a representation that was, as to the Mono Thread, materially false.

6.11 By marketing the Miracu Mono Thread for cosmetic use in non-surgical aesthetic settings — including cosmetic studios and aesthetic facilities operated by non-physician practitioners, such as Face Studio Wow — Defendants placed an implantable medical device requiring sterile surgical technique into the hands of practitioners who had not been adequately warned of the specific sterile conditions necessary to prevent bacterial contamination of the product and the insertion site — conditions that would have been required as a condition of any lawful FDA clearance for cosmetic use. Defendants' marketing and distribution of the product for off-label cosmetic use in non-surgical aesthetic environments — without the sterile technique guidance, antiseptic preparation protocols, and infection control standards necessary to safely introduce an implantable foreign body into subdermal facial tissues outside a surgical setting — was a producing cause of Plaintiffs' injuries.

F. The Procedures and Resulting Injuries

6.12 Between April 16 and April 23, 2024, Lisa Stiles, R.N., performed PDO Mono Thread placement procedures on each Plaintiff at Face Studio Wow, 1800 N. Haskell Avenue, Suite 200, Dallas, Texas 75204. The procedures were performed under the medical direction of Dr. Dee Martinez, M.D., whose name appears in each Plaintiff's patient record as the directing physician. The procedures were performed on the following dates: Laura Pitlik on April 16, 2024; Kimberly Williams and Kelsie Spears on April 17, 2024; and Barbara Thompson on April 23,

2024.

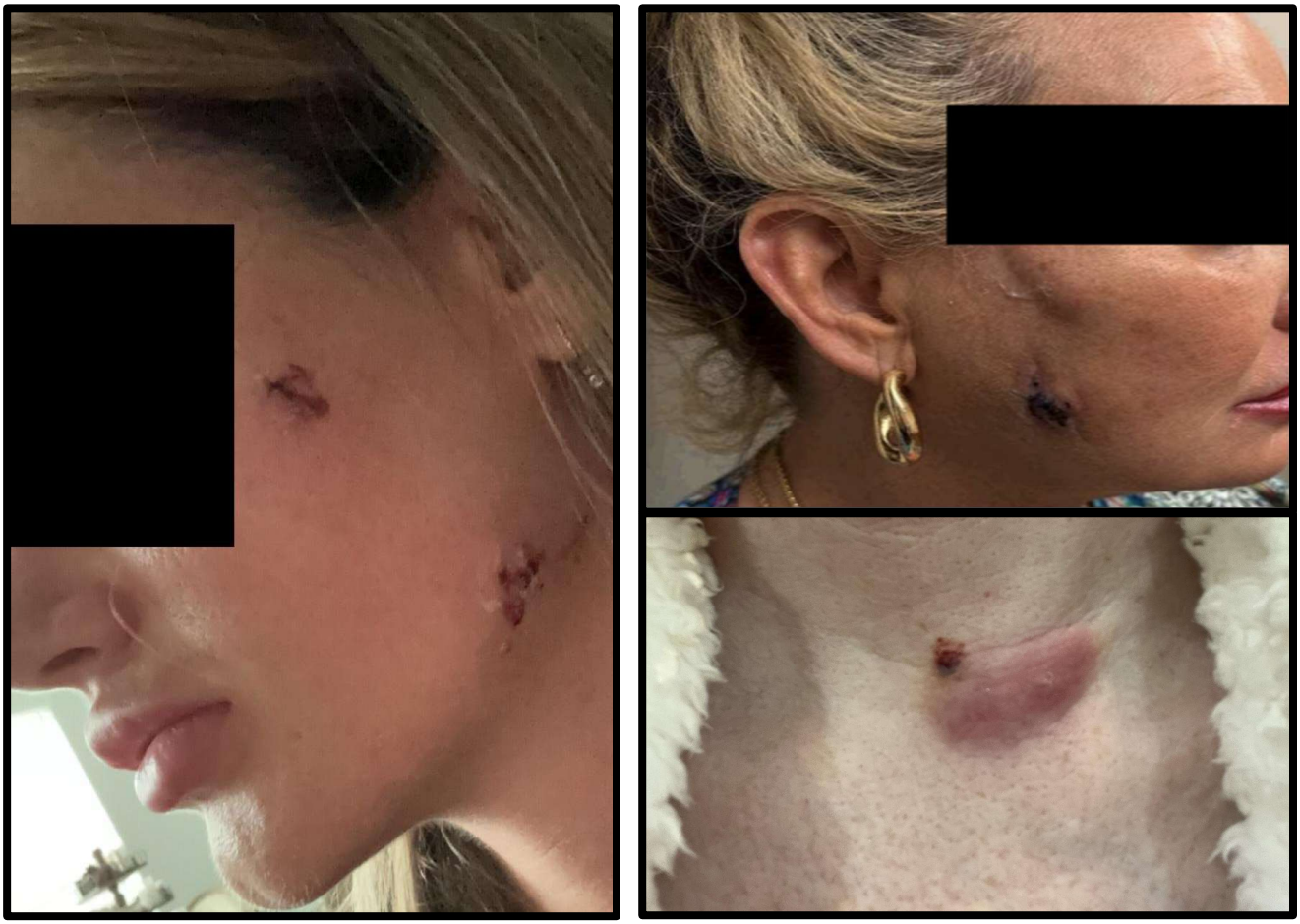
6.13 In each procedure, Stiles inserted Miracu Mono Thread PDO sutures (Model No. 29036B, Size 29GX30mm, Lot 533B1B) bilaterally into the upper cheek and lower jawline areas of each Plaintiff for the stated purpose of cosmetic enhancement and tissue tightening. All four procedures used product from the same 25-count pouch of Miracu Mono Thread.

6.14 Within approximately two weeks of their respective procedures, each Plaintiff developed signs and symptoms of infection at the thread insertion sites, including swelling, erythema, induration, and abscess formation. Subsequent microbiological cultures obtained from Plaintiffs' facial abscesses identified Mycobacterium abscessus — a rapidly growing, antibiotic-resistant non-tuberculous mycobacterium that is environmentally ubiquitous and known to cause treatment-resistant soft tissue and wound infections, particularly in immunocompromised and post-procedural contexts. The cases were identified as a cluster infection involving multiple patients who underwent PDO thread procedures at Face Studio Wow during the same one-week period using product from the same product pouch.

6.15 Each Plaintiff required one or more of the following as sequelae of the Mycobacterium abscessus infection: surgical incision and drainage of facial abscesses; surgical removal of foreign bodies (thread fragments); placement of a peripherally inserted central catheter (PICC line) for long-term intravenous antibiotic administration; and prolonged courses of intravenous and oral antibiotic therapy, including combination regimens due to antibiotic resistance. Plaintiffs' injuries include permanent facial scarring, disfigurement, and the ongoing need for additional reconstructive and corrective procedures.

6.16 Following each Plaintiff's procedure, Lisa Stiles, R.N. acknowledged in communications to Plaintiffs that four patients from the same product pouch had developed the

same reaction, and attributed the cluster infection to 'a bad batch' of threads — an acknowledgment that the specific product lot, Lot 533B1B, was contaminated."



VII. CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT(Against Defendant Feel Tech Co., Ltd.)

7.0 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

7.1 Defendant Feel Tech Co., Ltd. is the "manufacturer" of the Miracu Mono Thread within the meaning of Tex. Civ. Prac. & Rem. Code § 82.001(4), as the entity that designed, produced, assembled, packaged, and labeled the product and placed it into the stream of commerce

for distribution and sale in the United States.

7.2 The Miracu Mono Thread, Model No. 29036B, Lot 533B1B, deviated in its construction or quality from its specifications, planned output, and applicable quality system requirements under 21 C.F.R. Part 820 (FDA Quality System Regulation) in a manner that rendered it unreasonably dangerous. Specifically, and on information and belief:

7.3 The product as manufactured and distributed was not sterile, or had compromised sterility, at the time it left Feel Tech's control, in violation of the sterility standards applicable to implantable medical devices under 21 C.F.R. §§ 820.70, 820.72, and 820.80, and the product's own labeling designating it as a sterile, single-use device.

7.4 The product was manufactured, processed, sterilized, and/or packaged under conditions or using processes that did not conform to the validated manufacturing and quality specifications applicable to a sterile single-use implantable medical device, resulting in a product that reached the point of use in a condition that caused or contributed to Mycobacterium abscessus contamination and infection at the thread insertion sites of each Plaintiff.

7.5 The specific product lot — Lot 533B1B — exhibited a pattern of contamination-related adverse events: each of the four patients treated from the same 25-count product pouch during a one-week period developed the same Mycobacterium abscessus infection at the thread insertion sites. This cluster pattern, involving the same practitioner, the same product pouch, and multiple patients on separate treatment dates across one week, is consistent with a product-level contamination that was present when the product left Feel Tech's manufacturing and distribution chain.

7.6 The product reached each Plaintiff without substantial change in condition from the time it left Feel Tech's control. The product's labeling designated it as sterile and single-use, and

it was used consistently with those designations and with its marketed indication for cosmetic thread placement.

7.7 The manufacturing defect rendered the product unreasonably dangerous to ordinary consumers, including Plaintiffs, who had no means of detecting or protecting themselves from a contaminated implantable medical device.

7.8 The manufacturing defect was a producing cause of each Plaintiff's Mycobacterium abscessus infection and resulting injuries, damages, and disfigurement.

COUNT II: STRICT PRODUCTS LIABILITY — MARKETING DEFECT / FAILURE TO WARN(Against All Defendants)

7.9 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein. Defendants Feel Tech, DBM, BENEV, and Aesthetics each had actual or constructive knowledge of the following risks associated with the Miracu Mono Thread:

a) The risk of serious bacterial infection, including infection with antibiotic-resistant environmental organisms including Mycobacterium abscessus, arising from the use of the product in non-surgical aesthetic settings without application of the sterile surgical technique standards applicable to implantable foreign body procedures.

b) The risk that the Miracu Mono Thread would be used in non-surgical aesthetic settings — including cosmetic studios, aesthetic clinics, and similar facilities operated by non-physician practitioners without surgical infrastructure — by practitioners who lacked the sterile technique training and facility resources necessary to prevent contamination of an implantable medical device, because Defendants actively marketed and promoted the product for use in exactly those settings

c) The risk that practitioners using the product in cosmetic aesthetic settings would not implement the antiseptic skin preparation, sterile field maintenance, and single-use compliance

protocols necessary to prevent introduction of environmental organisms — including Mycobacterium abscessus — into the subdermal facial tissues at the thread insertion sites.

d) The risk that the product was being used for cosmetic tissue lifting and tightening procedures — a use expressly excluded from every FDA clearance applicable to the product — in the absence of the clinical evidence base and procedure-specific safety guidance that would be required for a lawful FDA clearance for cosmetic use.

7.10 The product was promoted and sold for a use --- cosmetic facial tissue enhancement and tightening in non-surgical aesthetic settings, including the type of cosmetic aesthetic facility where Plaintiffs were treated--- that was expressly excluded from every applicable FDA clearance. This exclusion is not an artifact of the product's pre-clearance status in April 2024; it is a permanent feature of the product's regulatory profile: K251414, the Mono-specific clearance obtained in October 2025, contains the identical restriction as K172602, stating the product 'is not intended for lifting and supporting tissues.' Defendants marketed the product for a use it was never cleared for and never will be cleared for under any existing clearance.. By marketing the product for cosmetic use in non-surgical settings, Defendants placed an implantable foreign body device into clinical environments that lacked the sterile technique infrastructure and trained personnel necessary to prevent bacterial contamination — without providing the warnings and instructions necessary to address that risk.

7.11 The Miracu Mono Thread's packaging and labeling, and any instructions for use accompanying the product, failed to provide adequate warnings of the following specific, foreseeable risks:

a) The risk of Mycobacterium abscessus and other environmental organism infections arising from use of an implantable PDO thread suture in non-sterile or inadequately sterile

conditions in aesthetic medspa environments.

b) The specific preprocedural antiseptic skin preparation and sterile field protocols required to prevent bacterial contamination of the product and the insertion site in cosmetic thread placement procedures.

c) The specific infection risks associated with use of the product in cosmetic tissue enhancement and lifting procedures — the very use for which Defendants marketed the product — as compared to the use for which it was cleared (soft tissue approximation in a surgical setting with established sterile technique protocols).

d) The risks arising from failure to discard an opened sterile pouch after use and the prohibition on storing or reusing any component from a single-use sterile package across multiple patients or multiple treatment sessions — including the specific risk that bacterial contamination of an opened sterile pouch would be introduced into the subdermal facial tissues of subsequent patients treated from the same opened package.

e) The fact that the product was being distributed and sold for off-label cosmetic use without a valid FDA 510(k) clearance for that specific device type and without the safety evidence base that clearance would require.

7.12 An adequate warning — one that specifically identified the risk of antibiotic-resistant bacterial infection in cosmetic aesthetic settings, required specific antiseptic preparation protocols, and prohibited cosmetic tissue lifting use in non-surgical environments absent validated sterile technique compliance — would have altered the conduct of the practitioners at Face Studio Wow and would have prevented or materially reduced the risk of Plaintiffs' infections. The absence of such warnings caused the product to be used in conditions under which the infection risk was not recognized or mitigated.

7.13 The marketing defect and failure to warn was a producing cause of each Plaintiff's Mycobacterium abscessus infection and resulting injuries, damages, and disfigurement.

COUNT III: NEGLIGENCE PER SE — VIOLATION OF 21 U.S.C. § 331(Against Defendants Feel Tech, DBM, and BENEV)

7.14 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

7.15 Section 331 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a), prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. Section 331(k) prohibits the doing of any act with respect to a device while such device is held for sale after shipment in interstate commerce which results in such device being adulterated or misbranded. A device is "adulterated" under 21 U.S.C. § 351(f)(1)(B) if it is required to have premarket clearance and does not. A device is "misbranded" under 21 U.S.C. § 352(o) if it was not cleared for the intended use for which it is promoted and sold.

7.16 Defendants Feel Tech, DBM, and BENEV manufactured, imported, and distributed the Miracu Mono Thread in interstate commerce without a valid FDA 510(k) clearance for the specific device type — the non-barbed PDO monofilament suture — at the time of manufacture, importation, distribution, and use. As set forth above, K172602 covered only the barbed Miracu suture and K251414 was not obtained until October 2025. The distribution of the Miracu Mono Thread without a valid clearance for that device type was a prohibited act under 21 U.S.C. § 331(a) and (k).

7.17 The statute violated — 21 U.S.C. § 331 — was designed to protect patients like Plaintiffs from the precise type of harm Plaintiffs suffered: injury from a medical device that was

not subjected to the clinical and safety review that FDA premarket clearance requires, and that lacked the adequate labeling, warnings, and instructions for safe use that such review would mandate. Plaintiffs are among the class of persons the statute was intended to protect. The harm suffered — infection from an inadequately labeled and uncleared implantable device used in a non-surgical setting — is the type of harm the statute was intended to prevent.

7.18 The statutory violations described herein constitute negligence per se under Texas law. Each Defendant's violation of 21 U.S.C. § 331 was a proximate cause of each Plaintiff's injuries, damages, and disfigurement.

COUNT IV: NEGLIGENCE(Against All Defendants)

7.19 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

7.20 Each Defendant owed Plaintiffs a duty of reasonable care in the manufacture, design, testing, quality assurance, importation, distribution, marketing, promotion, and sale of the Miracu Mono Thread. That duty included the duty to ensure the product was manufactured, packaged, and distributed in compliance with applicable FDA quality system regulations, 21 C.F.R. Part 820; the duty to obtain valid FDA clearance for the specific device type before distributing it in interstate commerce; the duty to warn practitioners of the specific risks of using the product in non-surgical cosmetic settings without adequate sterile technique protocols; and the duty to refrain from marketing the product for uses outside its cleared indications without the safety evidence required to support those uses.

7.21 Each Defendant breached its duty of care in one or more of the following particulars:

a) Failing to adequately warn practitioners of the risk of serious bacterial infection —

including infection with Mycobacterium abscessus and other antibiotic-resistant environmental organisms — associated with use of the Miracu Mono Thread in non-surgical cosmetic aesthetic settings without the sterile technique, antiseptic skin preparation, and infection control protocols applicable to invasive procedures involving the subdermal introduction of foreign bodies.

b) Failing to ensure the product was manufactured, packaged, and distributed in a sterile condition free from bacterial contamination in accordance with applicable FDA quality system regulations, 21 C.F.R. Part 820, for sterile single-use implantable medical devices.

c) Failing to provide adequate instructions for use, including specific instructions requiring preprocedural antiseptic skin preparation, maintenance of a sterile field during insertion, strict compliance with the single-use device designation for all components including insertion needles, and prohibition on cosmetic tissue lifting use in non-surgical environments without validated sterile technique compliance.

d) Marketing, promoting, and distributing the Miracu Mono Thread for cosmetic facial enhancement and tissue tightening procedures — a use expressly excluded from every FDA clearance applicable to the product — without obtaining the separate clinical evidence, validated sterile technique protocols, and regulatory clearance required for safe cosmetic use of an implantable suture device.

e) Manufacturing, importing, and distributing the Miracu Mono Thread in the United States without a valid FDA 510(k) clearance for the non-barbed Mono Thread device type, in violation of 21 U.S.C. § 331.

f) Representing, directly and through authorized distributor channels, that the Miracu Mono Thread had FDA 510(k) clearance for its marketed cosmetic uses — a representation that was materially false and misleading, as the only existing clearance (K172602) covered only barbed

threads and expressly excluded tissue lifting, and the Mono-specific clearance (K251414) was not obtained until eighteen months after Plaintiffs were injured.

7.22 Each of the foregoing breaches, individually or in combination, was a proximate cause of each Plaintiff's Mycobacterium abscessus infection and resulting injuries, damages, and disfigurement.

COUNT V: SELLER LIABILITY UNDER TEX. CIV. PRAC. & REM. CODE § 82.003(Against Defendants DBM Corporation USA, BENEV Company Inc., and Aesthetics Distribution, LLC)

7.23 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

7.24 Defendants DBM Corporation USA, BENEV Company Inc., and Aesthetics Distribution, LLC are each a "seller" of the Miracu PDO Mono Thread within the meaning of Tex. Civ. Prac. & Rem. Code § 82.001(3), as each is engaged in the business of distributing or otherwise placing, for any commercial purpose, the Miracu PDO Mono Thread into the stream of commerce for use or consumption.

i. Liability Under § 82.003(a)(5) — Misrepresentation

7.25 Defendants DBM, BENEV, and Aesthetics are liable as nonmanufacturing sellers pursuant to Tex. Civ. Prac. & Rem. Code § 82.003(a)(5) on the following grounds:

7.26 WHAT WAS REPRESENTED: Defendants DBM and BENEV, through their distribution websites (www.MIRACUUSA.com and www.dbmcorpusa.com), product marketing materials, sales communications, and authorized distributor channels, made express factual representations to healthcare practitioners and aesthetic providers in the United States, including Texas, that the Miracu Mono Thread had received FDA 510(k) clearance and was cleared for cosmetic thread placement and facial tissue enhancement procedures in aesthetic clinic settingss — made express factual representations that the Miracu Mono Thread had received FDA 510(k)

clearance and was cleared for cosmetic thread placement and facial tissue enhancement procedures in aesthetic clinic settings. DBM publicly announced on December 11, 2018, that it obtained "FDA 510(k) Market Clearance for Miracu PDO Threads" as "the first PDO thread to receive 510(k) clearance in the U.S. market," representing to practitioners and the medical aesthetic market that the Miracu product — including the Mono Thread — was lawfully cleared for commercial distribution and use. On information and belief, Defendant Aesthetics made similar representations to its member accounts in Texas in the course of marketing and selling the product to them.

7.27 WHY THE REPRESENTATIONS WERE FALSE: These representations were materially false and incorrect. K172602, the only clearance that existed in April 2024, covered only the barbed Miracu suture — a distinct device from the Mono Thread — and expressly stated the product is "not intended for lifting and supporting tissues." No valid FDA 510(k) clearance for the Miracu Mono Thread as a distinct device type existed at the time of sale, distribution, and use. The Mono Thread was not lawfully cleared for commercial distribution; its distribution without valid clearance was a prohibited act under 21 U.S.C. § 331. Defendants' representation that the Miracu product had FDA clearance for its marketed cosmetic uses was false in every material respect.

7.28 RELIANCE AND CAUSATION: Practitioners who purchased and used the Miracu Mono Thread, including the practitioners at Face Studio Wow in Dallas, Texas, relied on Defendants' representations that the product had FDA clearance for cosmetic PDO thread procedures. That reliance was reasonable: FDA clearance is a fundamental prerequisite for the lawful commercial distribution of a medical device in the United States, and healthcare practitioners are entitled to rely on distributors' representations regarding the regulatory status of products they market and sell. Had the practitioners known that the product lacked FDA clearance

for the cosmetic Mono Thread procedure — and therefore had not been reviewed for safety, effectiveness, or labeling adequacy for that procedure — they would not have purchased or used the product for the cosmetic procedures at issue. Plaintiffs were injured as a result of the very procedures for which the product was marketed without valid clearance and for which adequate safety-related warnings and instructions had never been established through the FDA clearance process.

ii. Liability Under § 82.003(a)(7) — Manufacturer Not Subject to Jurisdiction

7.29 Plaintiffs have effected, or will effect, service of process on Defendant Feel Tech Co., Ltd. through the procedures prescribed under the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents. Service on Feel Tech is necessarily delayed due to the Hague Convention process. Pursuant to Tex. Civ. Prac. & Rem. Code § 82.003(a)(7)(B) and § 82.003(c), if, after proper service has been effected on Feel Tech through the Hague Convention, Feel Tech fails to answer or otherwise make an appearance within the time required by law, it is conclusively presumed for purposes of § 82.003(a)(7)(B) that Feel Tech is not subject to the jurisdiction of the Court. In that event, Defendants DBM Corporation USA, BENEV Company Inc., and Aesthetics Distribution, LLC shall bear full seller liability for the product defects described herein as provided by statute.

7.30 Independently, in the event the Court determines at any stage of this proceeding that it lacks personal jurisdiction over Feel Tech Co., Ltd. on any basis, § 82.003(a)(7)(B) provides that DBM, BENEV, and Aesthetics are liable as sellers in Feel Tech's stead. Plaintiffs expressly invoke the § 82.003(c) presumption and reserve all rights arising therefrom.

COUNT VI: GROSS NEGLIGENCE AND EXEMPLARY DAMAGES
(Against All Defendants)

7.30 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth

herein.

7.31 The acts and omissions of Defendants, when viewed objectively from the standpoint of each actor at the time of the occurrence, involved an extreme degree of risk, considering both the probability and the magnitude of the potential harm to others. Specifically:

a) Defendants manufactured, imported, distributed, and sold the Miracu Mono Thread for cosmetic tissue enhancement and tightening procedures in non-surgical aesthetic settings — procedures for which the product had no valid FDA clearance, for which the product's labeling explicitly disclaimed intended use, and for which no validated sterile technique or infection control protocols had ever been established or provided — with the knowledge that the product would be inserted subdermally into the faces of patients who could suffer severe, permanent injury if contamination occurred.

b) The FDA clearance process exists precisely to ensure that medical devices used in the manner Defendants promoted this product are safe for that use, are accompanied by adequate warnings and instructions, and are reviewed for the specific risks associated with the marketed indication. By marketing the product for a use expressly excluded from every applicable FDA clearance --- and representing it as having clearance it did not have --- Defendants deliberately bypassed the safety review that would have identified and required mitigation of the specific risks that caused Plaintiffs' injuries. The subsequent grant of K251414 in October 2025 confirms rather than cures this failure: that clearance, like its predecessor, expressly excludes tissue lifting and tightening, demonstrating that the cosmetic use Defendants promoted was never within any cleared indication.

c) Despite awareness of the cluster infection pattern — multiple patients developing the same antibiotic-resistant mycobacterial infection from the same product lot — Defendants

maintained that the injuries were attributable to "a bad batch," acknowledging the possibility of product-level contamination while failing to take meaningful remedial action to protect other patients.

7.32 Each Defendant had actual, subjective awareness of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of Plaintiffs and other patients. Each Defendant knew or had substantial reason to know: (a) that the Miracu Mono Thread lacked FDA clearance for the specific non-barbed Mono Thread device type at the time of distribution and use, and that every applicable FDA clearance --- both then and subsequently --- expressly excluded the cosmetic tissue enhancement use for which the product was marketed; (b) that the cleared indications for every applicable Miracu clearance expressly excluded tissue lifting and tightening; (c) that the product was being used in non-surgical aesthetic settings by practitioners who were not trained in or equipped for the sterile technique necessary to safely introduce an implantable foreign body into subdermal facial tissues; and (d) that the product's labeling and instructions for use were inadequate to communicate the specific infection risks of cosmetic use in non-surgical environments. Defendants' conduct in proceeding with the marketing, distribution, and sale of the product for uncleared cosmetic use, in the face of this knowledge, constitutes gross negligence as defined by Tex. Civ. Prac. & Rem. Code § 41.001(11).

7.33 Plaintiffs are entitled to recover exemplary damages from each Defendant in an amount to be determined by the jury, subject to the limits set forth in Tex. Civ. Prac. & Rem. Code § 41.008.

VIII. DAMAGES

8.0 As a direct and proximate result of the conduct of Defendants described herein, each Plaintiff has suffered, and will continue to suffer, the following actual damages:

a) Physical pain and suffering, both past and future;
b) Mental anguish, both past and future;
c) Physical impairment, both past and future;
d) Disfigurement, both past and future, including permanent facial scarring arising from the Mycobacterium abscessus infection and the surgical procedures required to treat it;
e) Medical expenses, both past and future, including but not limited to the costs of surgical drainage procedures, PICC line placement, intravenous and oral antibiotic therapy, infectious disease specialist consultation, follow-up care, and the cost of future reconstructive and corrective procedures;
f) Lost wages and loss of earning capacity, both past and future.

8.1 Each Plaintiff also seeks exemplary damages as permitted by Tex. Civ. Prac. & Rem. Code § 41.003, based on Defendants' gross negligence as described herein.

8.2 Plaintiffs also seek prejudgment and post-judgment interest at the highest rates permitted by law, and all costs of court.

IX. CONDITIONS PRECEDENT

9.0 All conditions precedent to Plaintiffs' right to bring this action and to recover herein have been performed or have occurred. Plaintiffs' claims are product liability claims against product manufacturers and distributors and do not constitute health care liability claims under Tex. Civ. Prac. & Rem. Code § 74.001 as to the Defendants named herein. The notice requirements of Tex. Civ. Prac. & Rem. Code § 74.051 are not applicable to product liability claims against nonhealthcare-provider Defendants.

X. DEMAND FOR JURY TRIAL

10.0 Pursuant to the Seventh Amendment to the United States Constitution and Fed. R. Civ. P. 38(b), Plaintiffs hereby demand a trial by jury on all issues so triable. The jury demand fee will be tendered contemporaneously with the filing of this Complaint.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Barbara Thompson, Kimberly Williams, Kelsie Spears, and

Laura Pitlik respectfully request that the Court enter judgment in their favor and against Defendants, jointly and severally where permitted by law, for the following relief: Actual and compensatory damages as set forth above, in an amount to be determined by the jury, and in excess of $75,000 as to each Plaintiff; Exemplary damages as permitted by Tex. Civ. Prac. & Rem. Code § 41.003, in an amount to be determined by the jury; Prejudgment and post-judgment interest at the maximum rate permitted by law; Costs of court and other litigation expenses as permitted by law; Such other and further relief, in law or in equity, to which Plaintiffs may show themselves justly entitled.

Respectfully submitted,

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