March 7, 2023

Hans Biomed Corporation
℅ Sarah Fitzgerald
Senior Consultant, Quality and Regulatory Affairs
Emergo by UL
2500 Bee Caves Road, Building 1
Suite 300
Austin, Texas 78746

Re: K220549
Trade/Device Name: MINT Product Family (Including MINT, MINT Lift, and MINT-I Sutures), MINT Lift ML 1043, MINT Lift ML 1013, MINT Lift 1019, MINT Lift Mini 1014
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: February 8, 2023
Received: February 8, 2023

Dear Sarah Fitzgerald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220549

Device Name
MINT Product Family

Indications for Use *(Describe)*
MINT Product Family (Including MINT, MINT Lift, and MINT-I Sutures) are comprised of PDO and are indicated for use in soft tissue approximation where use of a barbed absorbable suture is appropriate.

These sutures are also indicated for use in face suspension surgery to temporarily fixate the cheek sub dermis in an elevated position.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K220549 510(k) Summary

MINT Product Family

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

February 23, 2023

4. Device Identification

Trade/Proprietary Name:	MINT Product Family (Including MINT, MINT Lift, and MINT-I Sutures)
Common/Usual Name:	Polydioxanone absorbable surgical suture
Classification Name:	Polydioxanone absorbable surgical suture
Review Panel:	General & Plastic Surgery
Regulation Number:	878.4840
Class:	Class II
Product Code:	NEW

5. Device Description

MINT Product Family Sutures are synthetic, absorbable, sterile, surgical sutures comprised of polydioxanone. These sutures are available in a range of lengths and thicknesses and have bi-directional

barbs which hold the suture in position and exert tension throughout the length of the suture. These sutures are provided sterile. They degrade and reabsorb over time.

6. Indications for Use

MINT Product Family (including MINT, MINT Lift, and MINT-I Sutures) are comprised of PDO and are indicated for use in soft tissue approximation where use of a barbed absorbable suture is appropriate.

These sutures are also indicated for use in face suspension surgery to temporarily fixate the cheek sub dermis in an elevated position.

7. Equivalence Claimed to Predicate Device

The MINT Product Family (including MINT, MINT Lift, and MINT-I Sutures) is equivalent to the MINT Product Family (cleared in K192423), manufactured by Hans Biomed Corporation. Miracu (K172602), PDS Barbed Suture, PDO MAXX Threads (K190245), Demetech PDO Absorbable Suture (K082097), MINT (K130191), and Silhouette InstaLift (K163676) are provided as reference devices.

Comparison of Characteristics

	Subject MINT Product Family Sutures	**Predicate MINT Product Family Sutures K192423**	**Reference Devices (As noted below)**	**Comparison**
Product Code / Regulation	NEW / 21 CFR 878.4840	NEW / 21 CFR 878.4840	NEW / 21 CFR 878.4840 (K082097, K130191, K172602, K190245) or GAM / 21 CFR 879.4493 (K163676)	Same or Equivalent Both product codes are for absorbable, sterile, flexible surgical sutures for soft tissue approximation. GAM is simply for a different material.
Intended Use	Absorbable surgical sutures for use in soft tissue	Absorbable surgical sutures for use in soft tissue	Absorbable surgical sutures for use in soft tissue (All)	Same
Indications for Use	MINT Product Family (including MINT, MINT Lift, and MINT-I Sutures) are comprised of PDO and are indicated for use in soft tissue approximation where use of a barbed absorbable suture is appropriate.		The MINT comprised of PDO is indicated for use in soft tissue approximation where use of an absorbable suture is appropriate (K130191)	Equivalent Slight rewording for clarity. No difference in meaning.
	These sutures are also indicated for use in face suspension surgery to temporarily fixate the cheek sub dermis in an elevated position.	MINT is indicated for use in mid-face suspension surgery to temporarily fixate the cheek subcutaneous fat layer and SMAS layer in an elevated position for the	The Silhouette Instalift device is indicated for use in mid-face suspension surgery to temporarily fixate the cheek sub dermis	Equivalent Published clinical data demonstrates no difference in safety or effectiveness.

	Subject MINT Product Family Sutures	**Predicate MINT Product Family Sutures K192423**	**Reference Devices (As noted below)**	**Comparison**
		treatment of moderate to severe nasolabial folds.	in an elevated position. (K163676)	
Suture Material	Polydioxanone	Polydioxanone	N/A (Subject same as predicate)	Same
Suture Characteristics	Synthetic absorbable monofilament with bi-directional barbs along the long axis	Synthetic absorbable monofilament with bi-directional barbs along the long axis	N/A (Subject same as predicate)	Same
Sterilization	Ethylene oxide	Ethylene oxide	N/A (Subject same as predicate)	Same
Size (USP)	Compliant with USP Standard Suture Sizes	Compliant with USP Standard Suture Sizes	N/A (Subject same as predicate)	Same
Contact Type	Implant, Absorbable	Implant, Absorbable	N/A (Subject same as predicate)	Same
Contact Duration	>30 Days	>30 Days	N/A (Subject same as predicate)	Same
Suture Diameter	Compliant with USP <861> requirements	Compliant with USP <861> requirements	N/A (Subject same as predicate)	Same
Suture Tensile Strength	Compliant with USP <881> requirements	Compliant with USP <881> requirements	N/A (Subject same as predicate)	Same
Suture-Needle Attachment	Compliant with USP <871> requirements	Compliant with USP <871> requirements	N/A (Subject same as predicate)	Same
Accessories	Optional tapered / Blunt needle or cannula	Optional tapered / blunt needle	Optional sharp or blunt needle / cannula (K172602 and K190245)	Equivalent
Accessory Material (Patient Contacting)	Stainless Steel (SUS 304)	Stainless Steel (SUS 304)	N/A (Subject same as predicate)	Same

This submission is to add the following to the products cleared under K192423 and K130191:

- Expanded indications for use
- Additional MINT Suture types / models
- Additional accessory to facilitate suture implantation

8. Non-Clinical Performance Data

Additional testing was conducted and relevant scientific data collated for this 510(k) in alignment with the FDA guidance "Class II Special Controls Guidance Document: Surgical Sutures," confirming that the design output meets the design inputs and specifications for the sutures.

All differences form the previous cleared 510(k)s for MINT sutures are equivalent or the same as for reference devices. Testing and evaluation was conducted in alignment with "Class II Special Controls Guidance Document: Surgical Sutures." Testing conducted included biocompatibility evaluation and testing per ISO 10993-1, ISO 10993-5, and ISO 10993-10; tensile strength testing to confirm USP <881> monograph strength; barb holding strength testing; suture-needle attachment strength testing to confirm USP <871>

monograph strength; needle corrosion resistance testing; needle flexural stress testing; cannula pull testing; and needle penetration testing.

Additionally, the change in terminology to cheek sub dermis is supported as the language is the same as that used for the reference device.

The results of the non-clinical performance testing demonstrate substantial equivalency between the subject and predicate device.

9. Animal Performance Data

No animal testing was conducted for this submission.

10. Clinical Performance Data

Published clinical literature was reviewed and utilized to support his submission. A comprehensive literature search was conducted and 10 relevant articles were found and evaluated.

Published literature regarding clinical experience from regions where the additional suture types and accessories are legally available was provided to substantiate the differences from the subject and predicate device. This published literature includes the difference in indications for use, which expanded claims from the predicate and reference from use in mid-face suspension surgery to use in face suspension surgery. This consisted of published articles supporting the safety and effectiveness of the changes from the predicate, with an aggregate number of more than 500 patients with clinical follow-up of a minimum of 3 months, including some patients with follow-up of 22+ months. Patient demographics varied, and most patients were Asian and female. Most patients experienced significant improvements in appear and, when evaluated, were satisfied with the procedure. Complications were generally mild, self-resolving, and similar to those caused by similar devices and/or the procedure itself. Complications included skin dimpling, pain, edema, ecchymosis, pustule formation, swelling, tightness / discomfort, alopecia, thread exposure / extrusion, depression at entry point, irregularities of the skin, facial asymmetry, and infection.

Results of the clinical literature support that the subject sutures are substantially equivalent to the predicate device in performance, safety, and effectiveness.

11. Statement of Substantial Equivalence

All testing and evidence confirms that the subject device does not raise any new questions related to the safety or effectiveness and that the device is at least as safe and at least as effective as the predicate device for the intended use and indications for use. Therefore, the device can be considered substantially equivalent to the predicate device.