September 9, 2020

Hans Biomed Corporation
℅ Michael Dun
Senior Consultant, Quality and Regulatory Affair
Emergo Global Consulting, LLC
2500 Bee Cave Road Building 1, Suite 300
Austin, Texas 78746

Re: K192423
Trade/Device Name: MINT Product Family
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: June 18, 2020
Received: August 10, 2020

Dear Michael Dun:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192423

Device Name
MINT™

Indications for Use *(Describe)*
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 treatment of moderate to severe nasolabial folds.

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.

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510(k) Summary

MINT™ Product Family

1. Submission Sponsor

Hans Biomed Corporation

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Republic of Korea

Contact: Lucy Choi

Title: General Manager

2. Submission Correspondent

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Contact: Michael Dun

Title: Senior Consultant, Quality and Regulatory Affairs

3. Date Prepared

9 September2020

4. Device Identification

Trade/Proprietary Name:	MINT™ Product Family
Common/Usual Name:	Absorbable surgical suture
Classification Name:	Absorbable polydioxanone surgical suture
Regulation Number:	21 CFR §878.4840

Product Code: NEW

Device Class: Class II

Classification Panel: General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

The primary predicate is the Silhouette InstaLift™ device cleared under K163676 by Silhouette Lift, Inc. The reference device is the original MINT™ device cleared under K130191 by Hans Biomed Corporation. Neither the predicate nor reference devices have been subject to a design-related recall.

6. Indication for Use Statement

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 treatment of moderate to severe nasolabial folds.

7. Device Description

The MINT™ device is a sterile synthetic absorbable surgical suture comprised of polydioxanone, $(C_4H_6O_3)_n$. Polydioxanone has been found to be nonantigenic and to elicit only a slight tissue reaction during absorption. The pigment of the violet dye is D&C Violet No.2 (21CFR §74.3602). MINT™ is available in a range of gauge sizes and lengths.

Each suture has bi-directional barbs along the long axis of the suture monofilament. The MINT™ Synthetic Absorbable PDO suture approximates tissues, without the need to tie surgical knots, by using the opposing barbs on the suture surface to embed in the tissues after the surgeon precisely places the suture within the tissues. Barbed suture lifting is a minimally invasive surgical technique for facial rejuvenation

While the formation of barbs in the MINT™ reduces the tensile strength relative to non-barbed suture material of the same size, tying knots in non-barbed suture materials also reduce their effective strength. For this reason, the strength of the MINT™ can be compared with USP knot strength of non-barbed sutures and the USP size of MINT™ is 1 while its tensile strength is equivalent to that of USP 2-0, as demonstrated under the original 510(k) for the MINT™ device (K130191).

The MINT™ Product Family includes models which are supplied with needles. For those models supplied with a needle, designated as “Lifting Thread Combined with needle” in the MINT™ Product Family instructions for use, the needle is used to make the insertion point and for threading of the suture in the patient’s dermis.

8. Substantial Equivalence Discussion

The MINT™ Product Family is currently indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate (K130191). The purpose of this submission is to obtain clearance of a new indication for the MINT™ Product Family for use in "lifting" procedures which includes variants supplied with needles. Due to the difference in intended use, the cleared MINT™ device family (K130191) is presented as a reference device in this submission while the cleared Silhouette InstaLift™ device family (K163676) is presented as the predicate as it has an identical intended use to that for the subject MINT™ device and includes variants supplied with needles with identical composition to the needles supplied with certain variants of the subject device. Additionally, while the predicate device is comprised of a different material (poly glycolide/L-lactide) and has a different number of barbs to that used in the subject device (polydioxanone (PDO)) questions of biocompatibility and clinical effectiveness are identical. Therefore, different questions of safety and effectiveness are not raised with the subject device in relation to these difference in technological characteristics.

While there are differences in the indications for use between the subject MINT™ Product Family and the predicate Silhouette InstaLift™ device family (K163676), these differences do not constitute differences in intended use or raise different questions of safety and effectiveness. Both devices are absorbable surgical sutures for use in soft tissue indicated for mid-face suspensions surgery to temporarily fixate the cheek in an elevated position. Both devices achieve nasolabial fold depth reduction as it is a clinical outcome of mid-face suspension surgery, as reported in the following published literature, copies of which accompany this submission:

1. Noone, R.B. (2006) Suture Suspension Malarplasty with SMAS Plication and Modified SMASectomy: A Simplified Approach to Midface Lifting. Plast. Reconstr. Surg. 117: 792.

2. Benito, J., et al. (2011) Facial Rejuvination and Improvement of Malar Projection Using Sutures with Absorbable Cones: Surgical Technique and Case Series. Aesth. Plast. Surg. 35: 248-253.

3. Paul, M. D. et al. (2006) The Evolution of the Midface Lift in Aesthetic Plastic Surgery. Plast. Reconstr. Surg. 117: 1809-1827.

The following table compares the MINT™ Product Family to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device and shown by clinical and other scientific data presented in this submission.

Table 5A – Comparison of Characteristics

Manufacturer	**Submission Device** **Hans Biomed Corporation**	**Predicate Device** **SILHOUETTE LIFT, INC**	**Significant Differences**
Trade Name	**MINT™**	**Silhouette InstaLift™**	

Manufacturer	**Submission Device** **Hans Biomed Corporation**	**Predicate Device** **SILHOUETTE LIFT, INC**	**Significant Differences**
Trade Name	**MINT™**	**Silhouette InstaLift™**	
510(k) Number	K192423	K163676	Not applicable
Product Code	NEW	GAM	Different; The difference in Product Code does not raise new questions of safety and effectiveness. Both product codes cover absorbable surgical sutures.
Regulation Number	21 CFR 878.4840	21 CFR 878.4493	Different; The difference in Regulation Number does not raise new questions of safety and effectiveness. Both regulations cover absorbable, sterile flexible surgical sutures that are intended for use in soft tissue approximation, coated or uncoated, and with or without a standard needle attached.
Regulation Name	Suture, Surgical, Absorbable, Polydioxanone	Suture, Absorbable, Synthetic, Polyglycolic Acid	Different; The difference in Regulation Name does not raise new questions of safety and effectiveness. Both regulations cover absorbable, sterile flexible surgical sutures that are intended for use in soft tissue approximation, coated or uncoated, and with or without a standard

Manufacturer	**Submission Device** **Hans Biomed Corporation**	**Predicate Device** **SILHOUETTE LIFT, INC**	**Significant Differences**
Trade Name	**MINT™**	**Silhouette InstaLift™**	
			needle attached.
Intended Use	Absorbable surgical sutures for use in soft tissue	Absorbable surgical sutures for use in soft tissue	Identical
Indication for use	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 treatment of moderate to severe nasolabial folds.	The Silhouette InstaLift™ device is indicated for use in mid-face suspension surgery to temporarily fixate the cheek subdermis in an elevated position.	Similar. While there are differences, these do not constitute differences in intended use or raise different questions of safety and effectiveness. Both devices are absorbable surgical sutures for use in soft tissue indicated for mid-face suspension surgery to temporarily fixate the cheek in an elevated position. Both devices achieve nasolabial fold depth reduction as it is a clinical outcome of mid-face suspension surgery, as reported in published literature referenced in this 510(k).
Raw Material	Polydioxanone suture Stainless steel (SUS 304) needle	Poly glycolide/L-lactide suture Stainless steel (SUS 304) needle	Different; While there are differences in suture material to the predicate device K163676, these do not raise new questions of safety and effectiveness. Biocompatibility data on file for the reference MINT™ device family K130191 demonstrate the device's

Manufacturer	**Submission Device** **Hans Biomed Corporation**	**Predicate Device** **SILHOUETTE LIFT, INC**	**Significant Differences**
Trade Name	**MINT™**	**Silhouette InstaLift™**	
			biocompatibility while clinical data presented in this submission also demonstrate equivalent safety and performance.
Suture Characteristic	Synthetic Absorbable Monofilament	Synthetic Absorbable Monofilament	Identical
Technique of Deployment	Needle-based deployment	Needle-based deployment	Identical; Both include variants supplied with needles.
Technological Characteristic	Bi-directional barbs along the long axis of the suture monofilament	Bi-directional barbs along the long axis of the suture monofilament	Identical
Sterilization	Ethylene Oxide	Ethylene Oxide	Identical
Size (USP)	1-0	1-0	Identical
Absorbable	Absorbable	Absorbable	Identical
Patient contact	Implant	Implant	Identical
Duration of contact	Over 30 Days	Over 30 Days	Identical
Number of barbs per linear length of suture	20 barbs per 10cm in all sutures.	8 barbs in 30cm sutures. 12 barbs in 27.5cm sutures. 16 barbs in 26.8cm sutures.	Different; While there are differences in the number of barbs to the predicate device K163676, these devices are substantially equivalent as no new questions of safety and effectiveness are raised, as demonstrated by barb holding strength testing and clinical data presented in this submission.

Manufacturer	**Submission Device** **Hans Biomed Corporation**	**Predicate Device** **SILHOUETTE LIFT, INC**	**Significant Differences**
Trade Name	**MINT™**	**Silhouette InstaLift™**	
Barb Holding Strength (Average ± Standard Deviation)	20.94 ± 3.93 N	9.90 ± 0.93 N	Different; While there are differences in the average barb holding strength to predicate device K163676, the differences do not raise new questions of safety and effectiveness as the average barb holding strength for the subject MINT™ device is superior to that of the predicate. Clinical data presented in this submission also demonstrate equivalent safety and performance.
Barb shape	Cog shape	Cog shape	Identical
Barb size	0.601mm	0.601mm	Identical
Barb direction	A section and B section is opposite direction	A section and B section is opposite direction	Identical
Pattern of the barbs	Bi-directional barbs along the long axis of the suture	Bi-directional barbs along the long axis of the suture	Identical
Suture diameter	Compliant with USP <861> requirements	Compliant with USP <861> requirements	Identical
Suture tensile strength	Compliant with USP <881> requirements	Compliant with USP <881> requirements	Identical
Suture-Needle attachment	Compliant with USP <871> requirements	Compliant with USP <871> requirements	Identical

9. Non-Clinical Performance Data

Additional testing was conducted and relevant scientific data collated for this 510(k). Previous tests performed on the MINT™ reference device (K130191) included those for overall design, sterilization, biocompatibility, and the physical and performance testing as described in the guidance entitled *Class II Special Controls Guidance Document: Surgical Sutures,* confirming that the design output meets the

design inputs and specifications for the sutures. These data also apply to the subject device, in all aspects except the expanded indications for use and provision of variants with needles.

The non-clinical performance testing performed on the subject device MINT™ Product Family variants including needles included physical and performance and real-time stability testing. This testing was focused on generating scientific data to support the inclusion of the needles in addition to generating scientific data to support the expansion of suture variants in order to demonstrate compliance with USP <861> Suture diameter, USP <871> Suture-Needle attachment, and USP <881> Suture tensile strength requirements.

Additional comparative barb holding strength testing was performed to demonstrate that the MINT™ Product Family displays superior barb holding strength to that for the Silhouette InstaLift™ predicate device (K163676).

The results of non-clinical performance testing demonstrate substantial equivalency between the MINT™ Product Family (K192423) and the predicate Silhouette InstaLift™ device (K163676) as they both comply with all the requirements of USP <861> Suture diameter, USP <871> Suture-Needle attachment, and USP <881> Suture tensile strength, and that the MINT™ Product Family displays superior barb holding strength to that for the Silhouette InstaLift™.

10. Animal Performance Data

In vivo studies in animal models to demonstrate absorption and mechanical strength of the subject device were performed.

The in vivo absorption study was completed on 30 rats prepared and anesthetized in accordance with the procedure and was performed on Monosorb, identical to the sutures used in the MINT™ Product Family. The results of this study indicated in vivo absorption of the sutures occurs between 180~220 days post-implantation.

The in vivo mechanical strength study was completed on rats prepared and anesthetized in accordance with the procedure and performed on MINT™ barbed suture. The results of this study indicated that tensile strength retention of MINT™ (USP 1) was 44.5% at 6 weeks and was unable to be measured at 10 and 12 weeks post-implantation due to severe degradation. Based on the results of this study, the breaking strength retention of MINT™ is considered to be approximately 50% at 6 weeks.

11. Clinical Performance Data

A prospective clinical study was conducted to evaluate safety and effectiveness of the MINT™ Product Family to support mid-face suspension surgery to fixate the cheek sub dermis in an elevated position. The aim of this study was to evaluate the surgical outcomes associated with using MINT™ for improving nasolabial folds.

In this study, 62 male and female subjects were assessed pretreatment and compared to 4, 8, 12, and 24 weeks following treatment using the previously validated and published 5-grade Wrinkle Severity Rating Scale (WSRS) score and rating by independent, blinded assessors. The correction of nasolabial folds using MINT™ was evaluated using blinded evaluator Global Aesthetic Improvement Scale (GAIS) ratings.

The primary effectiveness evaluation was carried out at 12 weeks after surgery by comparing the photos of nasolabial folds of the patients in the study group by blinded evaluators. Twenty-four weeks were set for final safety and effectiveness evaluation period. The primary effectiveness evaluation was carried out at 12 weeks after surgery by comparing the photos of nasolabial folds of the patients in the study group.

The ratio of subjects in the study group who showed wrinkle improvement (WSRS: below -1 point) by independent evaluation at 12 weeks after the application of test device, the primary effectiveness endpoint, was analyzed. The results showed 59 subjects (96.72%) in FA set showed improvement (WSRS: below -1 point) and the lowest confidence level of 20.95% was greater than 0, indicating superiority.

The results of secondary effectiveness evaluation showed the ratio of the subjects in FA who showed improvement (WSRS: below -1 point) by the evaluation of independent evaluators after the application of test device was 100% (61 subjects) at week 4, 96.72% (59 subjects) at week 8 and 90.16% (55 subjects) at week 24. The ratio of the subjects in FA who showed improvement (WSRS: below -1 point) by the evaluation of testers was 100% (61 subjects) at week 4, 8, 12 and 24. This tendency was represented in the results of an analysis of PP test.

When comparing the WSRS evaluated by independent evaluators at 4, 8, 12 and 24 weeks after the application of test device with baseline, the baseline of FA set was 3.30 $\pm$ 0.45 points; the difference in the mean of WSRS in comparison with baseline at each point was -1.56 $\pm$ 0.43 points at week 4, 1.41 $\pm$ 0.48 points at week 8, -1.23 $\pm$ 0.41 points at week 12, and -1.20 $\pm$ 0.45 points at week 24, indicating a decrease over time and statistically significant difference in comparison with baseline at all points of time ($p<0.001$). When comparing WSRS evaluated by testers at 4, 8, 12 and 24 weeks after the application of test device with the baseline by point of time, the mean of WSRS in FA set before the application of medical device was 3.21 $\pm$ 0.41 points; the difference in the mean of WSRS in comparison with the baseline at each point of time was -1.23 $\pm$ 0.42 points at week 4 and -1.25 $\pm$ 0.43 points at 8 weeks, indicating an increase in wrinkle improvement. It was -1.18 $\pm$ 0.39 points at week 12 and -1.16 $\pm$ 0.37 points at week 24 after the application of test device, indicating that the difference in the mean of WSRS after 12 weeks became smaller than that at week 8. Also, there was the statistically significant difference in comparison with the baseline at all points of time ($p<0.0001$).

The mean of GAIS in FA set assessed by evaluators at 12 weeks and 24 weeks after the application of test device in comparison with baseline was 1.93 $\pm$ 0.36 points at week 12 and 1.85 $\pm$ 0.44 points at week 24, indicating the high satisfaction level of evaluators. When analyzing the distribution of GAIS point evaluated by evaluators at each point of time, 2 points (very much improved) took the greatest

proportion- 53 subjects (86.89%) at week 12, and 48 subjects (78.69%) at week 24. The mean of GAIS evaluated by the subject at 12 and 24 weeks after the application of test device was 1.92 ± 0.63 points in FA set, indicating a high satisfaction level of subjects. When analyzing the distribution of GAIS point evaluated by evaluators at each point of time, 2 points took the greatest proportion - 35 subjects (57.38%) at week 12 and 32 subjects (52.46%) at week 24.

Results of the clinical investigation support the indications for the use of the MINT™ Product Family to support mid-face suspension surgery to fixate the cheek sub dermis in an elevated position and is effective for the improvement of facial wrinkles. Clinical study conclusion confirms that the device is safe and effective as used according to the instructions for use.

12. Statement of Substantial Equivalence

The subject device is identical to the predicate in relation to indications for use. The indications for use for the subject device were evaluated in a clinical study which demonstrated acceptable performance and safety, thereby supporting a finding of substantial equivalence. This clinical data also demonstrates that no different questions of safety and effectiveness were raised for differences in the number of barbs between the subject and predicate devices. Differences in raw material are addressed by the data presented in the 510(k) for the reference device along with the presented non-clinical, animal, and clinical performance data. The needles supplied with the subject device were evaluated in pre-clinical (bench) performance testing which demonstrate acceptable performance and safety.