June 14, 2019

Silhouette Lift Inc.
Anthony Dibernardo
Senior Director, Quality Assurance and Regulatory Affairs
1 Technology Drive F211
Irvine, California 92618

Re: K191299
Trade/Device Name: Silhouette Featherlift / Silhouette Lift
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW, GAM
Dated: May 10, 2019
Received: May 14, 2019

Dear Mr. Dibernardo:

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,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting)
Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
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)*
K191299

Device Name
Silhouette Lift Suture

Indications for Use *(Describe)*

Silhouette Lift Sutures are for use in Midface suspension surgery to 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 9

510(k) Summary

1. Submitter Details

Current 510(k) number: K171005
510(k) Holder: Silhouette Lift Inc,
1 Technology Drive Suite F211, Irvine CA 92618
Facility Registration No: 3007009755
Date of Preparation: May 2019

Contact Details:
Name: Silhouette Lift Inc,
Address: 1 Technology Drive Suite F211, Irvine CA 92618
Contact person: Anthony DiBernardo
Telephone No: +1 949 724 2074

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and MDR 21 CFR Part 807.81, Silhouette Lift Inc hereby notifies the Food and Drug Administration (FDA) of a change to the shelf life of the Silhouette Lift Suture (K171005) in USA.

2. Device Name

The device name as per the original 510(k) is Featherlift Silhouette Suture.
The trade name utilized in the USA is Silhouette Lift Suture.
The part numbers that are to be modified under this trade name are:

SMS 01-PP-3.0.1-B-S
SMS 02-PP-2.0.1-B
SMS 03-PP-3.0.1-CL
SMS 06-PP-3.0.1-B-L

Regulation Name: Nonabsorbable polypropylene surgical suture
Regulation Number: 21 CFR 878.5010
Regulatory Class: II
Product Code: GAW, GAM

3. Substantial Equivalence
The modified Silhouette Lift device is substantially equivalent to Featherlift Silhouette Suture (original name for the device) cleared under K060414 and amended under K171005. The change to the device is limited to changes made to the shelf life (extension to 18months).

No changes have been made to the intended use or fundamental scientific technology and therefore the supporting information on sterilization, biocompatibility, and clinical data remain unchanged from the original application.

The only modification made to the predicate device is the modification to the shelf life of the device. The details and reasons for which are detailed within this 510(k).

The subject device does not raise any new questions of safety and effectiveness and therefore is substantially equivalent to the predicate.

4. Device Description
Silhouette Lift Sutures are non-absorbable, sterile sutures.

SMS 01-PP-3.0.1-B-S, SMS 03-PP-3.0.1-CL and SMS 06-PP-3.0.1-B-L are made of 40.5 cm USP 3.0 size polypropylene suture with 6 cones made of a resorbable material (Lactide / Glycolyde 82:18) affixed to the suture.
SMS 02-PP-2.0.1-B is a 37.3cm USP 2.0 size polypropylene suture with 10 cones made of resorbable material (Lactide / Glycolyde 82:18) affixed to the suture.

Attached to one end of each of the sutures is a straight needle and to the opposite end is a ½ circle taper needle.
All products are supplied sterile (EO) for single use only. Silhouette Lift Sutures elicit a minimal acute inflammatory reaction in tissue that is followed by gradual encapsulation.

5. Intended Use/Indications for Use
Silhouette Lift Sutures are for use in midface suspension surgery to fixate the cheek sub dermis in an elevated position.

The intended use of the modified device is identical to the predicate, Silhouette Lift Suture/ Featherlift Silhouette Suture cleared under K060414 and amended under K171005.

6. Technological Characteristics

The technological characteristics of the modified Silhouette Lift Sutures remain unchanged from those described in the original K060414 and amended K171005.

Overall Design	Polypropylene monofilament with LG 8218 cones
Product Material(s):	82 :18 poly(glycolide/Llactide (cones); and polypropylene monofilament
Product design and method of operation:	Polypropylene monofilament with LG 8218 cones
Method of Construction	Extruded polypropylene monofilament and injection molded PLG 8218 cones
Sterilization Process:	EO Sterilization
Outline of surgical procedure:	Surgical insertion (0.5 inch) in the scalp; suture and needle inserted from entry site to below the jaw line; cones grab and hold facial tissue in elevated position.
Environment required for insertion:	Physician's office or out-patient surgical center.

7. Performance Testing

Results obtained in the stability study were in accordance with the acceptance criteria defined in the protocol and demonstrated continued sterility, package integrity and device functionality over the 18 months requested in this 510(k).

Performance data provided within the stability report confirms compliance to:

- Peak Tensile Force at Break USP <881>
- Monofilament Diameter USP <861>
- Swaging Test between Monofilament and Needle USP <871>
- Sterility USP <71>

This confirms that Silhouette Lift meets relevant USP specifications at the end of its shelf life and is equivalent to its predicate.

No clinical testing was conducted as part of this submission. Biocompatibility evaluation in according with ISO 10993-1 as performed on the predicate device remains valid and supportive for Silhouette Lift product with the extended shelf life, as there have been no new materials introduced, the materials in contact with tissues have not changed and the duration of contact remains, the same, therefore no additional testing was deemed necessary.