March 27, 2020

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

Re: K200140
Trade/Device Name: Silhouette Instalift
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: December 23, 2019
Received: January 21, 2020

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,

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)*
K200140

Device Name
Silhouette Instalift

Indications for Use *(Describe)*

The Silhouette Instalift device is indicated for use in mid-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.

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: K200140
510(k) Holder: Silhouette Lift Inc,
1 Technology Drive Suite F211, Irvine CA 92618
Facility Registration No: 3007009755
Date of Preparation: November 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 labelling of the Silhouette Instalift Suture (K163676) in USA.

2. Device Name

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

SMS 28-PLG-3.0.1-NA
SMS 29-PLG-3.0.1-NA
SMS 30-PLG-3.0.1-NA

Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulation Number: 21 CFR 878.4493
Regulatory Class: II
Product Code: GAM

3. Substantial Equivalence

The modified Silhouette Instalift device is substantially equivalent to previous Silhouette Instalift device cleared under K142061 and amended under K163676. The change to the device is limited to changes made to the labelling, which includes an additional contraindication.

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 labelling of the device. The details and reasons for which are detailed within this Special 510(k).

4. Device Description

Silhouette Instalift Sutures are absorbable, sterile sutures.

It is manufactured from a USP size 3-0 Poly/Glycolide/l-lactide suture material and an implantable grade of bioabsorbable PLGA resin (100% Poly (L-lactide-co-glycolide) (co-monomer ratio: L-Lactide =82mol%: glycolide=18mol%). The 30 centimeter suture (+- 10 %) (SMS 28-PLG-3.0.1- NA), 27.5 centimeter suture (+- 10 %) (SMS 29-PLG-3.0.1-NA) or 26.8 centimeter suture (+- 10 %) (SMS 30-PLG-3.0.1-NA) are attached to two 12 centimeter straight stainless steel needles.

All products are supplied sterile (EO) for single use only. Silhouette Instalift Sutures elicit a minimal acute inflammatory reaction in tissue that is followed by gradual encapsulation.

5. Intended Use/Indications for Use

The Silhouette Instalift device is indicated for use in mid-face suspension surgery to temporarily fixate the cheek sub dermis in an elevated position.

The intended use of the modified device is identical to the predicate, Silhouette Instalift cleared under K142061 and amended under K163676.

6. Technological Characteristics

The technological characteristics of the modified Silhouette Instalift Sutures remain unchanged from those described in the original K142061 and amended under K163676.

Overall Design	PLG 8218 monofilament and cones
Product Material(s):	PLG 8218 poly(glycolide/Llactide monofilament and cones
Product design and method of operation:	LG 8218 absorbable monofilament and absorbable cones
Method of Construction	Extruded PLG 8218 monofilament and injection molded PLG 8218 cones
Sterilization Process:	EO Sterilization
Outline of surgical procedure:	Surgical insertion using straight needles only – no incisions; Insertion through a puncture from the entry point to exit points, as determined by physician. Cones grab and hold facial tissue in elevated position.
Environment required for insertion:	Physician's office or out-patient surgical center.