DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 3, 2017

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

Re: K171005
Trade/Device Name: Silhouette Featherlift
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW, GAM
Dated: March 29, 2017
Received: April 4, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K171005

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.

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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: January 2017

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 Instructions for Use that accompanies 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. Predicate Device

Device Name:	FeatherLift Silhouette Suture.
Device Part Numbers:	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
510(k) Number:	K060414
Regulation Name:	Nonabsorbable polypropylene surgical suture.
Regulation Number:	21 CFR 878.5010
Regulatory Class:	II
Product Code:	GAW, GAM

FeatherLift Silhouette Sutures are non-absorbable, sterile devices.
The devices comprise a polypropylene monofilament with cones made of a resorbable material (Lactide / Glycolyde 82:18) affixed to it.
Attached to one end of the monofilament 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.

4. Substantial Equivalence

The modified Silhouette Lift device is substantially equivalent to Featherlift Silhouette Suture cleared under K060414. The change to the device is limited to changes made in the directions for use.

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 in the content of the Instructions for Use. The details and reasons for which are detailed within this Special 510(k) Change be effected.

Substantial Equivalence: Silhouette Lift and Featherlift Silhouette

Trade Name	Silhouette Lift (K171005)	FeatherLift Silhouette Suture (K060414)	Significant Difference
Overall Design	Polypropylene monofilament with LG 8218 cones	Polypropylene monofilament with LG 8218 cones	No Difference
Product Material(s):	8218 poly(glycolide/Llactide (cones); and polypropylene monofilament	8218 poly(glycolide/Llactide (cones); and polypropylene monofilament	No Difference
Product design and method of operation:	Polypropylene monofilament with LG 8218 cones	Polypropylene monofilament with LG 8218 cones	No Difference
Method of Construction	Extruded polypropylene monofilament and injection molded PLG 8218 cones	Extruded polypropylene monofilament and injection molded PLG 8218 cones	No Difference
Sterilization Process:	EO Sterilization	EO Sterilization	No Difference
Outline of surgical procedure:	Surgical insertion (.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.	Surgical insertion (.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.	No Difference
Environment required for insertion:	Physician's office or out-patient surgical center.	Physician's office or out-patient surgical center.	No Difference

5. 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.

6. 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 device is identical to the predicate, Featherlift Silhouette Suture (K060414).

7. Technological Characteristics

The technological characteristics of the Silhouette Lift Sutures remain unchanged from those described in K060414.

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 (.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.