DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 16, 2017

Silhouette Lift, Inc.
℅ Mr. Brian Young
Health Policy Associates, Inc
690 Canton Street
Suite 302
Westwood, Massachusetts 02090

Re: K163676
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: May 18, 2017
Received: May 19, 2017

Dear Mr. Young:

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)*
K163676

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.

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510(k) SUMMARY

Submitted by: Silhouette Lift, Inc.
A Sinclair Pharma Company
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Date Prepared June 15, 2017

Trade Name: SILHOUETTE INSTALIFT

Common Name: Absorbable surgical suture

Classification Name: Absorbable poly(glycolide/l-lactide) surgical suture

Regulation Number: 21 CFR 878.4493

Classification Product Code: GAM

Device Classification: II

Predicate Device:

The predicate is the original Silhouette Instalift device cleared under 510(k) number K142061 on April 24, 2015.

Device Description:

The Silhouette Instalift device consists of two Stainless Steel Surgical needles and an absorbable implant. The absorbable implant is available in three configurations, each consisting of a single monofilament that holds two bidirectional sets of 4, 6 or 8 cones. Both the monofilament and the cones are made from L- lactide/Glycolide bioresorbable resin material.

This device is supplied sterile for single use only.

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.

Intended Use:

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

Technological Characteristics (comparison to Predicate Device):

The subject Silhouette Instalift device is identical to the original 510(k) cleared predicate except that the instructions for use have been modified to include an additional optional implantation technique. The additional technique is less invasive and provides clinicians greater flexibility in the treatment of their patients.

Performance Testing Summary:

Nonclinical Testing:

The design, materials, manufacturing and sterilization processes are the same as the original predicate version of the device. No additional bench testing was required to support substantial equivalence of this labeling change.

Clinical Testing:

A prospective, clinical study was performed to assess treatment with Silhouette Instalift without use of a permanent, monofilament, anchor suture. In this study, 20 subjects were assessed pretreatment, and compared to 1, 8, and 12 weeks following treatment.

Subjects responded positively to subject-reported outcomes questions regarding their satisfaction with treatment. There was an improvement in cheek satisfaction and age appraisal through 12 weeks post-treatment using the validated patient-reported outcome FACE-Q measure. Additional details are provided in the Tables below:

Table 1: FACE-Q Satisfaction with Cheeks (N=20 Subjects)

Question	*1 = Very Dissatisfied; 2 = Somewhat Dissatisfied; 3 = Somewhat Satisfied; 4 = Very Satisfied*				
	Mean (SD)				
	Enrollment N=20	**Week 8 N=20**	**Change**	**Week 12 N=20**	**Change**
a. How symmetric (similar) your cheeks look?	2.45 (1.05)	3.20 (0.83)	0.75 (1.29)	3.30 (0.80)	0.85 (1.23)
b. How smooth your cheeks look?	2.40 (0.99)	3.00 (0.92)	0.6 (1.54)	3.00 (0.86)	0.60 (1.31)
c. How attractive your cheeks look?	2.15 (0.99)	3.00 (0.79)	0.85 (1.46)	3.20 (0.70)	1.05 (1.15)
d. The contour (outline) of your cheeks?	1.90 (0.91)	2.95 (0.83)	1.05 (1.23)	3.15 (0.75)	1.25 (1.12)
e. The youthful fullness of your cheeks?	1.95 (1.00)	3.00 (0.97)	1.05 (1.39)	3.15 (0.75)	1.20 (1.20)

* Compared to enrollment. Wilcoxon Signed Rank test.

Table 2: FACE-Q Age Appraisal-VAS (N=20 Subjects)

Question	**Years Mean (SD)**				
	Enroll-ment N=20	**Week 8 N=20**	**Change**	**Week 12 N=20**	**Change**
How many years younger or older do you think you look compared to your actual age?	+1 (6.9)	-2.9 (4.1)	-3.9 (5.3)	-2.4 (3.5)	-3.4 (5.3)

* Compared to enrollment. Wilcoxon Signed Rank test.

Canfield 3D Vectra M3 Face and Neck System was used in the post-treatment period to measure clinical results.

Table 3: Amount of Facial Lift in Both Cheeks (N=20 Subjects)

Timepoint	N (%); N=20				
	≥ 0.5 mm	**≥ 1.0 mm**	**≥ 1.5 mm**	**≥ 2.0 mm**	**≥ 2.5 mm**
Pre-Treatment (Visit 2)	10 (50%)	2 (10%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
1 Week Post-Treatment (Visit 4)	20 (100%)	16 (80%)	9 (45%)	1 (5%)	0 (0.0%)
8 Weeks Post-Treatment (Visit 6)	17 (85%)	10 (50%)	6 (30%)	2 (10%)	0 (0.0%)
12 Weeks Post-Treatment (Visit 7)	16 (80%)	7 (35%)	5 (25%)	4 (20%)	3 (15%)

The adverse events reported during the study were generally mild, of short duration, and resolved without sequelae. There were no serious adverse events, unanticipated problems, unanticipated adverse device effects, or deaths.

Substantial Equivalence:

The subject device utilizes the same design, materials, manufacturing and sterilization processes as the original predicate version of the device. The modified labeling technique was evaluated in a clinical study which demonstrated acceptable performance and safety thereby supporting a finding of substantial equivalence.