12/23/2022

Shineo Technology Co., Ltd
Wan-Chun Lai
CEO
5f, 207-4, Xinshu Road.,
New Taipei City, New Taipei City 24262
Taiwan

Re: K222748
Trade/Device Name: ShiNeo Silicone Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: MIB, LZK, FWP
Dated: October 9, 2022
Received: October 25, 2022

Dear Wan-Chun Lai:

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,

Deborah A. Fellhauer -S

Deborah Fellhauer
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222748

Device Name
ShiNeo Silicone Implant

Indications for Use *(Describe)*
ShiNeo Silicone Implant is intended for the augmentation or reconstruction of the nasal and/or chin contour

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person
Address: SHINEO TECHNOLOGY CO., LTD
Office address: 5F, 207-4, Xinshu Rd.,New Taipei City, 24262 Taiwan 10642, TAIWAN (R.O.C.)
Tel: (O) +886 (02)22021511
Fax numbers：+886 (02)22020331

Contact Person Name and Address:
Name: Chiao-Min Chang
Title: Regulatory Affairs
E-mail: cherryamigo46@gmail.com
Office address: 5F, 207-4, Xinshu Rd.,New Taipei City, 24262 Taiwan 10642, TAIWAN (R.O.C.)
Tel: (O) +886 963361392

Alternate Contact:
Name: Leo Huang
Title: General manager
Office address: 5F, 207-4, Xinshu Rd.,New Taipei City, 24262 Taiwan 10642, TAIWAN (R.O.C.)
Tel: (O) +886 (02)22021511
E-mail: oscar@shineotech.com

Date Summary Prepared: September 01, 2022
Type of submission: Traditional 510k

1. Device Name and Classification

Proprietary/Trade name	ShiNeo Silicone Implant
Common or Usual Name: Primary Product code:	MIB
Additional Product code	LZK, FWP
Regulation Number:	874.3620

Regulation Description:	Ear, nose, and throat synthetic polymer material.
Review Panel:	General & Plastic Surgery
Device Class:	II
Manufacturer information	Name: SHINEO TECHNOLOGY CO., LTD Address: 5F, 207-4, Xinshu Rd.,New Taipei City, 24262 Taiwan

2. Predicate Device(s)

Proprietary/Trade name	BioSiCar Silicone Implant K193392
Common or Usual Name: Primary Product code: Additional Product code	MIB LZK, FWP
Regulation Number:	874.3620
Regulation Description:	Ear, nose, and throat synthetic polymer material.
Review Panel:	General & Plastic Surgery
Device Class:	II
Manufacturer information	Name: SHINEO TECHNOLOGY CO., LTD Address: 5F, 207-4, Xinshu Rd.,New Taipei City, 24262 Taiwan

3. Device Description

ShiNeo Silicone Implant is a silicone implant used in facial surgery as nasal and/or chin implants. The ShiNeo Silicone Implant offers two major shapes to meet the needs in nasal and chin locations. The devices are also provided in various sizes and can be carved or cut to fit each patient. The ShiNeo Silicone Implant is individually packaged and sterilized by gamma radiation and is labeled for single use. ShiNeo Silicone Implant is ideal for use in soft tissue augmentation where the use of a soft silicone elastomer is appropriate.

4. Intended Use / Indications for Use

ShiNeo Silicone Implant is intended for the augmentation or reconstruction of the nasal and/or chin contour.

5. Substantial Equivalence

The ShiNeo Silicone Implant is identical to the predicate device and is as safe and

effective as the BioSiCar Silicone Implant. The Subject device has the same intended uses and indications, technological characteristics, principles of operation and manufactory process as its predicate device. There are no technological differences between the Subject device and its predicate devices resulting in no new issues of safety or effectiveness. Thus, the ShiNeo Silicone Implant is identical/substantially equivalent to the predicate device.

The subject and primary predicate devices are identical in the following ways:

• Indications for use	• FDA product codes
• Design intent	• Material formulation
• Classification	•Manufacturing Process
•Physico- chemical properties	•Sterilization process/Method/ Dose

6. Performance Data

The subject and predicate devices are identical and therefore, no performance testing is necessary to demonstrate substantial equivalence. This submission is to apply for a new trade name to the predicate device, BioSiCar Silicone Implant, K193392. Metalware Technology Corp, the submitter of K193392 has authorized SHINEO TECHNOLOGY CO., LTD. as the manufacturer legally authorized to market the predicate device. No new testing was provided.

7. Conclusions:

The ShiNeo Silicone Implant has the same intended uses, indications, technological characteristics, principles of operation and manufactory process as its predicate device. Thus, the subject device is identical/substantially equivalent to the predicate device.