July 20, 2020

Metalware Technology Corp.
Megan Chang
Product Manager
10F, No. 117, Minquan Rd., Xindian Dist.
New Taipei City, 231 Tw

Re: K193392
Trade/Device Name: BioSiCar Silicone Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIB
Dated: June 19, 2020
Received: June 22, 2020

Dear Megan Chang:

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193392

Device Name
BioSiCar Silicone Implant

Indications for Use *(Describe)*
BioSiCar 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.***

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*"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

**5.1 Type of Submission:** Traditional

**5.2 Date of Summary:** 11/26/2019

**5.3 Submitter:**


| | |
|---|---|
| **Address:** | Metalware Technology Corp.<br>10F, No.117, Minquan Rd., Xindian Dist., New Taipei City, 231, Taiwan (R.O.C.) |
| **Phone:** | +886-2-8667-2878 |
| **Fax:** | +886-2-8667-3686 |
| **Contact:** | Megan Chang<br>(megan.chang@metalware.com.tw) |


**5.4 Identification of the Device:**

| | |
|---|---|
| **Proprietary/Trade name:** | BioSiCar Silicone Implant |
| **Classification Product Code:** | |
| **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 |

**5.5 Identification of the Predicate Device:**

| | |
|---|---|
| **Predicate Device Name:** | SOFTXIL |
| **Manufacturer:** | Bistool |
| **Classification Product Code:** | MIB, LZK, FWP |
| **Regulation number:** | 874.3620 |
| **Device Class:** | II |
| **510(k) Number:** | K171851 |

## 5.6 Indications for Use / Intended Use of the Device

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

## 5.7 Device Description

**BioSiCar Silicone Implant** is a silicone implant used in facial surgery as nasal and/or chin implants. The **BioSiCar 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 **BioSiCar Silicone Implant** is individually packaged and sterilized by gamma radiation, and is labeled for single use. **BioSiCar Silicone Implant** is ideal for use in soft tissue augmentation where the use of a soft silicone elastomer is appropriate.

## 5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, BioSiCar Silicone Implant:

- Biocompatibility
- Performance & Shelf life
- Sterilization verification

All the test results demonstrate BioSiCar Silicone Implant meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

## 5.9 Clinical and Usability Testing

No clinical test data was used to support the decision of substantial equivalence.

## 5.10 Substantial Equivalence Determination

The subject device has similar intended use, same technology/mechanism of action, same claim of safety and performance, and similar technological specification as the predicate device, SOFTXIL (K171851). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

| **Item** | **Subject device** | **Predicate device** | **Substantial equivalence determination** |
|---|---|---|---|
| Manufacturer | Metalware Technology Corp. | BISTOOL | |
| Trade Name | BioSiCar Silicone Implant | SOFTXIL | |
| 510(k) No. | (to be assigned) | K171851 | |
| Product Code | MIB, LZK, FWP | MIB, LZK, FWP | ***Same*** |
| Regulation Number | 874.3620 | 874.3620 | ***Same*** |
| Intended Use | BioSiCar Silicone Implant is intended for the augmentation or reconstruction of the nasal and/ or chin contour. | SOFTXIL is intended for the augmentation or reconstruction of the nasal, malar, and or chin contour. | ***Similar*** Subject device is for nasal and/ or chin contour, while the predicate device has a wider usage that includes nasal, chin, and malar. |
| Indications for Use | | | |
| Material | Silicone elastomer | Silicone elastomer | ***Same*** |
| Design | Offers two major shapes to meet the needs in nasal and chin locations. | Offers various shapes to meet the needs in different locations. | ***Same*** |
| Function | Augmentation/ Reconstruction of the nasal and/or chin contour. | Augmentation of the nasal, malar, and or chin contour. | ***Similar*** Subject device is for nasal and or chin contour, while the predicate device has a wider usage that includes nasal, chin, and malar. |

| | | | |
|---|---|---|---|
| Size | Provided in various sizes (Please see Section 11 for detailed sizes). Can be carved or cut by the physician to fit each patient. | Provided in various sizes. Can be carved or cut by the physician to fit each patient. | ***Same*** |
| Usage | For single use only | For single use only | ***Same*** |
| Sterile | Yes | Yes | ***Same*** |

### 5.11 Similarity and Difference

The BioSiCar Silicone Implant has been compared with "SOFTXIL". The subject device has similar intended use, same technology/mechanism of action, same safety and performance, and similar technological specification as the predicate device. Although there are some different specifications between these devices, the performance test was completed and demonstrated similar test results (please refer to **Section 18**). The subject device has also undergone safety and performance tests, and the results complied with the test requests (referring to **Section 14 and 15**). Therefore, the differences between the subject device and the predicate device do not raise any new issue of substantial equivalence.

### 5.12 Conclusion

In conclusion, Metalware Technology Corp. believes that BioSiCar Silicone Implant maintains the same safety and effectiveness, and thus, is substantially equivalent to the predicate device.