March 16, 2018

Bistool
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine, California 92620

Re: K171851
Trade/Device Name: SOFTXIL
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: February 12, 2018
Received: February 13, 2018

Dear Ms. Chung:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

ATTACHMENT 1

Revised IFU Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K171581

Device Name
SOFTXIL

Indications for Use *(Describe)*

SOFTXIL is intended for the augmentation or reconstruction of the nasal, malar, 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

(K171581)

This 510(k) summary is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: Mar 14, 2018

1. **510K Applicant / Submitter:**
   BISTOOL
   9, Gwangnaru-ro 6-gil, Seongdong-gu,
   Seoul, Republic of Korea, 04796

   Contact Person: Eunhyun Bae, CEO
   Tel : +82-2-3446-7688

2. **Submission Contact Person**
   LK Consulting Group USA, Inc.
   690 Roosevelt, Irvine CA 92620
   Phone: 714.202.5789 Fax: 714.409.3357
   Contact: Priscilla Chung
   Email: juhee.c@lkconsultinggroup.com

3. **Device**
   - **Trade Name** : SOFTXIL
   - **Common Name**: Facial Silicone Implant
   - **Classification**: Elastomer, Silicone Block - 874.3620, Primary Product Code: MIB
     Additional product codes: LZK, FWP

4. **Predicate Device**
   AART Silicone Carving Block by Aesthetic and Reconstructive Technologies, Inc. (AART) (K021820)

5. **Device Description**
   SOFTXIL is injection molded silicone implants used in facial surgery as nasal, paranasal, and chin implants. The SOFTXIL offers various shapes to meet the needs in different locations.
   The devices are also provided in various sizes. The SOFTXIL is individually packaged and sterilized by ethylene oxide, and is labeled for single use. It has smooth surface with tapered ends. SOFTXIL is ideal for use in soft tissue augmentation where the use of a soft silicone elastomer is appropriate.

8. Indications for Use

SOFTXIL is intended for the augmentation or reconstruction of the nasal, malar, and or chin contour.

9. Substantial Equivalence Discussion:

The SOFTXIL is substantially equivalent in material, design, function, and performance to the AART Silicone Carving Block marketed by Aesthetic and Reconstructive Technologies, Inc. (AART). All products have identical intended uses and are offered in similar shapes and sizes. The size might be different between the devices, however, since the physician can carve or cut the material to fit each patient so that this difference does not raise an issue of safety and performance.

10. Performance Tests (Non-clinical)

Non-clinical bench tests were performed as followings:

- Sterilization Validation in accordance with ISO11737-1
- Shelf Life Test in accordance with ASTM F 1980; Appearance, Sterility, Tensile Strength, Elongation Percentage, Shore Hardness, Tearing Strength, Seal Strength, and Dye Penetration
- Biocompatibility Test in accordance with ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO 10993-11, USP<51>
- Performance Tests; Appearance, Dimensions, Extractable substances, Hardness (ASTM F881), Tensile Strength (ASTM F881), Elongation at Break (ASTM F881), Tear Strength (ASTM F881)

The test results of the tests support that the subject device is substantially equivalent to the predicate devices.

11. Conclusions:

Based on the information provided in this premarket notification, BISTOOL concludes that SOFTXIL is substantially equivalent to the predicate device as described herein in safety and effectiveness.