May 3, 2024

Sofregen Medical
Vivian Ruan
Quality and Regulatory Manager
175 Crossing Blvd, Suite 510
Framingham, Massachusetts 01702

Re: K240919
Trade/Device Name: Silk Voice (SMI-04)
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIX
Dated: April 3, 2024
Received: April 3, 2024

Dear Vivian Ruan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K240919

Device Name
Silk Voice (SMI-04)

Indications for Use *(Describe)*
Silk Voice® is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Silk Voice® injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication.

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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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the Silk Voice Vocal Cord Medialization System is provided below.

1. SUBMITTER

Sofregen Medical, Inc.
175 Crossing Blvd, Suite 510
Framingham, MA 01702

Contact Person: Vivian Ruan
Phone: 781-957-3152
Email: vruan@sofregen.com
Date Prepared: 01May2024

2. DEVICE

Name of Device: Silk Voice
Common Name: System, Vocal Cord Medialization
Classification Regulation: 21 CFR 874.3620
Regulatory Class: II
Product Code: MIX
Panel: Ear, Nose, and Throat

3. PREDICATE DEVICE

Predicate Device: Sofregen's Silk Voice (K180631)

4. DEVICE DESCRIPTION

Silk Voice® is a sterile, non-pyrogenic, cohesive implant provided in a prefilled syringe and is a ready to use product. Silk Voice is comprised of porous bioabsorbable silk particles suspended in an isotonic, aqueous formulation of cross-linked, high molecular weight hyaluronic acid (HA). The crosslinked HA gel acts as a carrier for the silk particles to facilitate delivery. The main component of Silk Voice is silk particles, manufactured exclusively from regenerated silk fibroin protein, isolated from purified silk fibers. When injected, Silk Voice provides immediate volume augmentation to the vocal fold tissue. The porous particles remain at the site of implantation, providing a scaffold for local tissue infiltration. This cellular infiltrated silk scaffold provides long-term restoration and augmentation.

Silk Voice prefilled syringes are provided in a kit with a catheter, that is designed for endoscopic delivery to the vocal fold. The catheter accessory provided in the kit is specifically designed for delivery of injectable materials into tissue during endoscopic procedures.

5. INDICATIONS FOR USE

Silk Voice® is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Silk Voice® injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication.

6. SUBSTANTIAL EQUIVALENCE

	Subject Device – Sofregen's Silk Voice (Formulation SMI-04)	**Predicate Device – Sofregen's Silk Voice (K180631)**
Classification Regulation	874.3620	Same
Product Code	MIX	Same
Intended Use	Vocal fold augmentation	Same
Indication for Use	Silk Voice is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Silk Voice injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing vocal fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication.	Same
Intended User	ENT Specialists	Same
Material Composition	Silk particles suspended in a cross-linked, aqueous formulation of HA	Same
Particle Size	250 ± 50 μm in diameter	380 ± 46 μm in diameter
Delivery Method	Injection via flexible catheter with needle, for endoscope delivery	Same
Delivery Device	Prefilled syringe	Same
Implant location	Vocal fold	Same
Implant duration	Long-term (>6 mo)	Same
Sterility	Provided sterile, SAL 10^{-6}	Same
Stability	Ambient temperature storage	Same
Biocompatibility	Biocompatible when injected into soft tissues	Same

The change to the silk particle size does not affect the safety or effectiveness assessment of the Silk Voice product and the subject device is substantially equivalent to the predicate device.

7. PERFORMANCE TESTING

7.1. Shelf-Life Testing

Shelf-life testing (device and packaging) was performed to support labeled expiration dating for Silk Voice®.

7.2. Bench Testing

All bench testing passed the acceptance criteria. The bench testing demonstrated that Silk Voice® delivery system meets pre-established design input requirements for its intended use.

Additional bench tests were performed to support a determination of substantial equivalence between the subject device and the predicate device.

- Particle size and circularity analysis
- Rheometry
- Extrusion force
- HA fragment test
- Particle concentration
- Residual Crosslinker Content
- pH
- Endotoxin
- Catheter leak test
- Catheter tensile strength

Sterilization validation for the steam sterilization cycle and the EtO sterilization cycle were conducted and SAL of 10^{-6} was demonstrated.

Biocompatibility test results of the predicate device submitted as part of the original submission (K180631) continue to support that Silk Voice® meets the requirements of ISO 10993 for its intended use.

8. CONCLUSION

Based on the same indications for use (and intended use), device functionality, usage, and performance, the subject Silk Voice® formulation is substantially equivalent to the predicate device (K180631).