December 18, 2024

Trey Thorsen
Regulatory Consultant
O'Connell & Myers, LLC
1110 Mark Ave
Carpinteria, California 93013

Re: K240763
Trade/Device Name: FirstFit Surgical Kit
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal Prosthesis (Taub Design)
Regulatory Class: Class II
Product Code: EWL
Dated: November 18, 2024
Received: November 18, 2024

Dear Trey Thorsen:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240763

Device Name

FirstFit Surgical Kit

Indications for Use *(Describe)*

The Blom-Singer® FirstFit™ Surgical Kit (FFSK) is indicated for use during surgical creation of primary or secondary tracheoesophageal puncture, dilation of the tracheoesophageal wall, and to guide the placement of the voice prosthesis for tracheoesophageal voice restoration following total laryngectomy.

The FFSK contains a sterile single use indwelling Blom-Singer® Indwelling Voice Prosthesis device intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

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.

510(k) Summary
Date: December 17, 2024

SUBMITTER

Freudenberg Medical, LLC
1110 Mark Ave.
Carpinteria CA 93013

Contact Person: Trey Thorsen
Email: trey@oconnellmyers.com
Phone: 850-450-3932

DEVICE

Name of Device: FirstFit™ Surgical Kit
Common or Usual Name: Prosthesis, Laryngeal (Taub)
Classification Name: Prosthesis, Laryngeal (Taub)
Regulation: 21 CFR 874.3730
Regulatory Class: II
Primary Product Code: EWL

PREDICATE DEVICES

Predicate: Provox® Vega Puncture Set, (K131947)

DEVICE DESCRIPTION

The FirstFit Surgical Kit (FFSK) is a kit for creating a primary or secondary TE puncture, with subsequent dilatation of that puncture to a width that facilitates placement of the included Blom-Singer® Indwelling Voice Prosthesis, cleared in K082206.

The FFSK is for transient use as an aid to a surgical operation to puncture and stent the tracheoesophageal septum. The FFSK is provided sterile (by ethylene oxide) in a sealed tray, ready to be introduced into the surgical field. Additionally, it is used to guide voice prosthesis placement in a total laryngectomized patient as a primary or secondary procedure. Puncture and placement should take place in a sterile field with the patient being under anesthesia.

The FFSK is designed for primary or secondary tracheoesophageal puncture (TEP) with retrograde voice prosthesis insertion. This kit includes: one (1) 13-gauge curved core puncture needle, one (1) 36-inch guidewire with rounded tips, one (1) pharynx protector tool with handle and notched cylinder, one (1) voice prosthesis inserter pre-loaded with a Blom-Singer® Indwelling Voice Prosthesis of the diameter and length specified on the package label.

The Blom-Singer® Indwelling Voice Prosthesis devices (VP) are indwelling devices primarily made of silicone, designed to provide voicing after total laryngectomy. The voice prostheses are placed in a surgically created fistula between the trachea and esophagus in order to divert air through the prosthesis valve to create voicing. The use of an indwelling device means that routine removal for cleaning by the

patient is not necessary, thus making it easier for the patient to maintain the device while reducing the risk of accidental dislodgment of the device.

INDICATIONS FOR USE / INTENDED USE

The Blom-Singer FirstFit Surgical Kit (FFSK) is indicated for use during surgical creation of primary or secondary tracheoesophageal puncture, dilation of the tracheoesophageal wall, and to guide the placement of the voice prosthesis for tracheoesophageal voice restoration following total laryngectomy.
The FFSK contains a sterile single use indwelling Blom-Singer® Indwelling Voice Prosthesis device intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

PATIENT POPULATION

For patients who had their larynx surgically removed.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The FirstFit Surgical Kit (FFSK) is a convenience kit for creating a primary or secondary TE puncture, with subsequent dilatation of that puncture to a width that facilitates placement of the included Blom-Singer® Indwelling Voice Prosthesis, cleared in K082206.

Biocompatibility testing

The biocompatibility evaluation for the FFSK was conducted in accordance with the FDA guidance, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, May 1, 1995, and International Standard ISO 10993-1 Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process, as recognized by FDA.

Performance Testing

The following testing was performed according to:

- Sterilization
    - Sterilization method: Ethylene Oxide
    - Validation method: overkill approach (half-cycle method) - per ISO 11135, ISO 10993-7, ISO 14937
- Shelf Life
    - Shelf life by accelerated aging- per ASTM F1980-21 (Accelerated Aging of Sterile Barrier Systems for Medical Devices)
    - Packaging Validation - Visual Inspection (per ASTM F1886), Burst Test (per ASTM F1140), Dye Penetration (per ASTM F1929), Peel Strength Testing (per TM-061)
- Biocompatibility - EN ISO 10993-1
- Bench testing – per internal protocols
    - Usability engineering IEC 62366-1: Cadaver Study - This study was performed under simulated-use conditions with 15 users performing 2 punctures & placements each on fresh cadaver tissue as a usability validation testing methodology for the FirstFit Surgical Kit to ensure the subject device can accommodate:
    - an anterograde tracheoesophageal puncture (TEP) (primary & secondary),

- a TEP dilation to allow for placement of 16Fr, 20Fr, & 22.5Fr voice prostheses
- a retrograde voice prosthesis insertion in the TEP (primary & secondary) During the study 3 out of 37 cadavers needed additional instrumentation for dilation to complete the placement of the voice prostheses. This result was indicative of post-mortem changes in cadaveric anatomy where it is no longer alive and has undergone significant changes due to the death and preservation by freezing process, including potential tissue stiffening, which could lead to difficulty dilating the tissue. This is supported in Hohmanna et al, 2018 that suggests fresh-frozen cadaver tissue exhibits a higher modulus (55.3MPa) of elasticity/stiffness compared to fresh tissue (25.6MPa) as observed in cadaveric long bicep tendons, which may suggest frozen cadaveric tissue used in our cadaver study exhibited a higher stiffness than what would be observed in a live patient.

The study concluded users can effectively place the FirstFit Surgical Kit with no tissue damage (ripping, tearing, etc.) during puncture and dilation of the tracheoesophageal wall and placement of the voice prosthesis.

Animal Studies
No animal data submitted.

Clinical Studies
No clinical data submitted.

CONCLUSIONS
Based on the study result and as a precaution, the FFSK's labelling has been updated to include a warning to "proceed with great care and abort the procedure if dilation of the TE puncture requires too much force". The addition of this waring aligns with the predicate's labeling.

The FFSK labeling also includes an additional recommendation for how to proceed if the procedure needs to be abandoned mid-way after the puncture has been created and dilated.

The physician must determine if the patient's tissue or anatomy is eligible for safe use of this kit as suggested by the contraindications, warnings, and precautions of our Instructions for Use either prior to procedure or during.

Freudenberg Medical believes the additional warning and recommendation for how to proceed certain cases, combined with the performance testing demonstrate that the subject device is substantially equivalent to the predicate.