December 6, 2019

TeleflexMedical, Inc
Lori Pfohl
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd, Suite 600 North
Morrisville, North Carolina 27560

Re: K192324
Trade/Device Name: Sheridan Spiral-Flex Endotracheal Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: August 22, 2019
Received: August 27, 2019

Dear Lori Pfohl:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192324

Device Name
Sheridan Spiral-Flex Endotracheal Tubes

Indications for Use *(Describe)*

Sheridan cuffed, uncuffed and reinforced tracheal tubes are designed for oral or nasal intubation and are indicated for airway management.

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.

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510(k) Summary

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560
Phone: 919-433-4831
Fax: 919-361-3939

B. Contact Person

Lori Pfohl
Senior Regulatory Affairs Specialist

C. Date Prepared

August 23, 2019

D. Device Name

Trade Name:	Teleflex Sheridan Spiral-Flex Tracheal Tube
Common Name:	Tube, Tracheal
Product Code:	BTR
Regulation Number:	CFR 868.5730
Classification Name:	Tracheal Tube
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device

This submission demonstrates substantial equivalence to the predicate device:

Sheridan Reinforced Tracheal Tube K844296 and Spiral-Flex Tracheal Tube K860105

F. Device Description

The **Sheridan Spiral-Flex Endotracheal Tubes** are spiral reinforced tracheal tubes that are inserted into the trachea via the mouth or the nose in order to establish a patent airway to allow ventilation. The subject device are sterile, single use devices. The tracheal tubes contain a compatible cuff, inflation line, pilot balloon and one-way valve. Each tracheal tube is supplied with an appropriately sized 15mm connector.

G. Indications for Use

Sheridan cuffed, uncuffed and reinforced tracheal tubes are designed for oral or nasal intubation and are indicated for airway management.

H. Contraindications

None

I. Substantial Equivalence

The subject device is substantially equivalent to the predicate devices with respect to intended use, technology and construction. The differences between the predicates and the subject devices are minor and any risks have been mitigated through testing. **Table 07.1** summarizes the differences between the subject and predicate device.

The subject devices are substantially equivalent to the predicate device:

Table 07.1 - Comparison of Predicate vs. Subject Devices

Features	Teleflex Sheridan Spiral-Flex Tracheal Tube (Subject Device)	Teleflex Sheridan Reinforced Tracheal Tube K844296 (Predicate Device 1)	Teleflex Sheridan Spiral-Flex Tracheal Tube K860105 (Predicate Device-2)
Classification Name	Tracheal Tube	Same	Same
Regulation Number	868.5730	Same	Same
FDA Procode	BTR	BTR	BTR
Class	II	Same	Same
Indication for Use	Sheridan cuffed, uncuffed and reinforced tracheal tubes are designed for oral or nasal intubation and are indicated for airway management.	Intended for airway management procedures requiring flexing of the neck	Airway management procedures requiring flexing of the neck
Contraindications	None	None	None
Single Use	Yes	Yes	Same
Population	Adult and Pediatric	Adult	Adult and Pediatric
Size Range	Cuffed oral/nasal 5.0-9.0 mm Uncuffed 3.0-5.0 mm	Oral 5.0 – 10.0 mm Nasal 5.0 – 9.0 mm	Uncuffed Oral 2.0 – 7.0 mm Nasal 2.0 – 7.0 mm

Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Valve System	Integral pilot balloon and valve	Same	Same
Shaft Material	PVC. Spiral wire completely embedded between two layers of PVC	Same	Same
Connector	Standard 15mm	Same	Same
Cuff Design	High Volume tapered cuff	Same	Same
Murphy Eye	Yes	Same	Same
Bite Block	Yes	Same	Same
Stylet	Yes	Same	Same
Tube Tip	Beveled	Same	Same
X-Ray Marker	At extreme end	Same	Same

J. Comparison to the Predicate

Table 7.1 illustrates the similarities and differences between the subject and predicate devices. The basic technological and operating principles are the same for both devices. Although the wording is not identical, both the subject and predicate devices are for airway management. Both the subject and predicate devices are intended for similar patient populations adult and pediatric, male and female. Both the subject and predicate devices are disposable, sterile, single patient use devices. As evidenced by comparison Table 7.1, above, the subject device is substantially equivalent to the predicate device. There are no significant differences that would affect safety and efficacy.

K. Performance Data

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Visual Inspection (No delamination on tip of reinforced tubes)
- Cuff inflation deflation test
- Inflation system leak test
- Cuff herniation test
- Pilot Cuff Pull test
- Simulated Use Test
- ISO 10993-1:2009 – Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process

The testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device.

The subject devices were tested to the requirements of ASTM F623.

L. Conclusion

The subject device has the same intended use and technological characteristics and construction as the predicate. Test results demonstrate that the subject device meets it's intended use. It is for these reasons that the subject device can be found substantially equivalent to the predicate devices.