Teleflex Medical
Lori Pfohl
Senior Regulatory Affairs Specialist
3015 Carrington Mills Blvd
Morrisville, North Carolina 27560

Re: K180253
Trade/Device Name: Sheridan Endobronchial Tubes
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: October 3, 2018
Received: October 5, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180253

Device Name
Sheridan Endobronchial Tubes

Indications for Use *(Describe)*
The SHERIDAN® Endobronchial Tube is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation. The SHERIDAN® Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.

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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"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

January 25, 2018

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
3015 Carrington Mills Bvld
Morrisville, NC 27560 USA
Phone: 919-491-8960
Fax: 919-433-4996

Contact Person

Lori Pfohl
Senior Regulatory Affairs Specialist

Device Name

Trade Name: Sheridan Endobronchial Tubes

Common Name: Bronchial Tube

Classification Name: Tube, Tracheal/Bronchial, Differential Ventilation (w/wo connector) (Class II per 21 CFR 868.5740, Product Code CBI)

Predicate Device

K141888 Rusch Endobronchial Tubes

Device Description

The Sheridan Endobronchial Tube is a sterile, single patient use PVC Double-Lumen Endobronchial Tube (also referred to as a DLT) that is inserted into the trachea via the mouth in order to selectively ventilate one lung.

Intended Use

The SHERIDAN® Endobronchial Tube is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation. The SHERIDAN® Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.

Contraindications

SHERIDAN® Endobronchial Tubes are contraindicated in patients with stenosis or obstruction of the main stem bronchus that will inhibit or prohibit accurate tube placement.

510(k) SUMMARY
January 25, 2018

Substantial Equivalence Comparison to Predicate

The proposed device is substantially equivalent to the predicate devices:

Features	Teleflex Medical Sheridan Endobronchial Tube (proposed)	Teleflex Medical Rusch Endobronchial Tube (predicate)
Classification Name	Tube, Trachael/Bronchial, Differential Ventilation (w/wo connector)	Same
Product Code	CBI	Same
Regulation Number	868.5740	Same
Indications for Use	The SHERIDAN® Endobronchial Tube is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation. The SHERIDAN® Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.	Rusch Endobronchial Tubes are used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia
Environment of Use	Hospital – OR and ICU	Same
Patient Population	Patients requiring one-lung isolation	Same
Contraindications	SHERIDAN® Endobronchial Tubes are contraindicated in patients with stenosis or obstruction of the main stem bronchus that will inhibit or prohibit accurate tube placement.	Left sides versions are contraindicated in patients with obstructions or stenosis in the left main bronchus. The right sided versions are contraindicated in patients with obstructions or stenosis in the right main bronchus. The versions with a carina hook are contraindicated for all procedures in the region of the carina
Design Features	Double lumen shaft, 2 cuffs, Stylet	Double lumen shaft, 2 cuffs, Stylet
Single Use	Yes	Yes
Size Range	28-41 French	26-41 French
Cuffed	Yes	Yes
Radiopaque	Yes	Yes
Connection to ventilation source	15 mm connector	15 mm connector
DLT Materials	PVC	PVC

- **Indications for Use –** The indications for use are considered to be identical. While the Sheridan indications for use is a bit more descriptive, both include identical uses.

- **Technology and construction -** The design, fabrication, shape, size, etc. is equivalent to the predicate. The designs of the proposed and predicate device consists of a double lumen tube with cuffs on each lumen, and corresponding side arm assemblies to inflate the cuffs.

- **Environment of use –** Identical for the proposed and predicate devices.

- **Patient Population -** While not specifically stated, the patient population is equivalent to the predicate

- **Materials** -All patient contacting materials are in compliance with ISO 10993-1. Testing included cytotoxicity, sensitization, intracutaneous activity, particulate matter, inorganic matter and VOC testing.

Comparison to Predicate Device:

The proposed **Endobronchial** tubes are substantially equivalent to the predicate devices with respect to indications for use, technology and construction. The differences between the predicate and the proposed devices are minor and any risks have been mitigated through testing. Additionally, the proposed device is made with the similar materials as the K141888 predicate**.**

Non-clinical Comparative Performance Testing

A brief summary of tests relied upon to demonstrate substantial equivalence to the predicate can be found in the table below:

Test	Reference to Standard (if applicable)	Principle of Test
15mm machine end Connector separation strength	N/A	The security of the attachment of the connector to the Endobronchial tube is tested by applying an axial separation force to the connector
Cuff resting diameter	ISO 5361	Verify that diameter size marked on pouch matches the diameter of the product
Cuff herniation	ISO 5361	Verify cuff is not going to distort beyond the nearest bevel
Cuff Burst Evaluation	N/A	The cuff restrained burst test is designed to ensure the cuff will not burst or rupture when inflated inside the trachea
Cuff Bond Strength	N/A	To evaluate the strength needed to separate the cuff from the tube
Side arm bonding strength	N/A	To evaluate the retention force of the inflation line connection to the Endobronchial tube

Substantial Equivalence Conclusion

The **Sheridan Endobronchial Tubes** have the same indications for use, patient population and technology of construction as the predicate device. Performance test results demonstrate that the proposed device meets its intended use. It is for these reasons that the proposed device can be found substantially equivalent.