DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 24,2014

Teleflex Medical, Inc.
James Cochie
Sr. Regulatory Affairs Specialist
2917 Weck Dr.
Research Triangle Park, NC 27709

Re: K141939
Trade/Device Name: Teleflex ISIS HVT Tracheal Tube, Cuffed With Subglottic Secretion Suction Port
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: October 28, 2014
Received: October 29, 2014

Dear Mr. Cochie,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141939

Device Name
TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port

Indications for Use *(Describe)*
The TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions.

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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510(k) SUMMARY

TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port

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

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8083
Fax: 919-433-4996

B. Contact Person

James Cochie
Sr. Regulatory Affairs Specialist

C. Date Prepared

November 24, 2014

D. Device Name

Trade Name: Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port

Common Name: Tracheal Tube

Classification Name: Tracheal Tube (W/Wo Connector) (21 CFR 868.5730, Product Code BTR)

E. Device Description

The Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is a single-use, sterile tracheal tube made of a polyvinyl chloride tube body, cuff inflation line and a compatible pilot balloon and one-way valve. A radiopaque line is incorporated into the full length of the tracheal tube. Each tracheal tube is supplied with an appropriately sized 15mm connector. The Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is sold in Murphy eye style. Each tube has a dorsal lumen with an opening above the cuff and a male suction connector port attached to the tube, which is close to the machine end of the tube. Access to the suction lumen is accomplished via a connection of the suction accessory pack (P/N 5-23000) directly to the male suction connector.

Section 29 – 510(k) Summary

F. Indications for Use

The Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions.

G. Target Population

This device is intended for use on adult patients

H. Intended Environment of use

This device is intended for locations where endotracheal intubation may be performed.

This product is single use only.

I. Contraindications

There are no known contraindications.

J. Substantial Equivalence

The modified Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is substantially equivalent to the predicate device:

Comparative Characteristics	Proposed Device, Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port	Predicate Device, Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port
Manufacturer	Teleflex Medical, Inc.	Teleflex Medical, Inc.
510(k) Number	N/A	K091761
Indications for Use	Identical	The Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions.
Main Tube	Identical	Yes
Inflation Line	Identical	Yes

Pilot Balloon	Identical	Yes
Bi-directional Valve	Identical	Yes
Cuff Balloon	Identical	Yes
15mm Connector	Identical	Yes
Male Suction Lumen Connector	Identical	Yes
Black Ink	• Printing Ink – 2405 Black Ink, Markem-Imaja • Solvent – Medical Ink Reducer, Colorcon	• Black Ink, Nazdar • Thinner, Nazdar • Retarder, Nazdar
Descriptive Size (ID)	Identical	6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm
Biocompatibility	Identical	Meets ISO 10993-1
Sterilization	Ethylene Oxide	Ethylene Oxide
Single Use	Yes	Yes
Shelf Life	12 Months (extending to 60 months as data becomes available)	12 Months (extending to 60 months as data becomes available)
Packaging	Identical	10 individually packaged in either banana pack or Tyvek pouches per dispenser box.

K. Non-clinical Comparative Performance Testing

Bench testing has been performed to verify that the performance of the proposed Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is substantially equivalent to the predicate device, and that the Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port will perform as intended.

Test Performed	Reference to Standard (if applicable)	Principle of Test
Ink adherence	ISO 5361, Section 5.3.2 (check compliance by inspection, as indicated in 6.4.1 of ASTM D3002.	Ink adherence is tested by application and removal of tape to the inked surface according to the test parameters and inspected to a rating scale.
Cytotoxicity	ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity	Tests the potential biological reactivity of a mammalian cell culture in response to exposure to the extract of the test article.
Irritation	ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Test the potential of the test article to produce primary skin irritation after topical application when extracted in sodium chloride for injections and cottonseed oil.

Sensitization	ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Test the potential of the test article to produce allergenic reaction when extracted in sodium chloride and cottonseed oil.
Extractables & Leachables	N/A	Assesses the ET tube relative to leachable/extractable profiles with GC/MS, LC/MS, LC/UV, ICP and FTIR under clinical use conditions

L. Substantial Equivalence

The modified Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is substantially equivalent in intended use, design, performance and principles of operation to the identified predicate device cleared under 510(k) K091761. The differences between the ISIS Tube and the predicated device are minor and raise no new issues of safety and efficacy. The ISIS Tube is substantially equivalent to the currently marketed predicate device.