510(k) SUMMARY

JUN 0 4 2014

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

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8050
Fax: 919-433-4996

B. Contact Person

Angela Bouse
Senior Regulatory Affairs Specialist

C. Date Prepared

June 3, 2014

D. Device Name

Trade Name:	SOFTECH® Plus $ETCO_2$ Cannula
Classification Name:	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Product Code:	CCK
Additional Product Code:	CAT
Regulation Number:	868.1400
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device

This submission demonstrates substantial equivalence to the predicate device Double Lumen Oxygen Delivery Gas Sampling Nasal Cannula, Hudson RCI Bi-Flo – K961150.

F. Device Description

The SOFTECH Plus $ETCO_2$ Cannula is a non-sterile disposable, single patient use device that acts as an adjunct to oxygen therapy with its primary function providing a means to deliver low flow oxygen, while sampling part of the patients exhaled gas.

The SOFTECH Plus $ETCO_2$ Cannula has a split nare blank with oxygen delivery through one nasal prongs while allowing sampling of the patient's exhaled gas from the corresponding nasal prongs.

G. Indications for Use

The Hudson RCI SOFTECH® Plus $ETCO_2$ Nasal Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate.

Patient Population: Infant, Pediatric, Adult

H. Technological Characteristics and Material Comparison to the predicate

The proposed SOFTECH Plus $ETCO_2$ Cannula is substantially equivalent to the predicate device listed above in that the indications for use, the intended use, and fundamental scientific technology remain unchanged. **Table 1** summarizes the differences between the proposed and predicate devices.

Table 1 - Differences Between the Proposed and Predicate Devices

Features	Predicate K961150 Double Lumen Oxygen Delivery Gas Sampling Nasal Cannula, Hudson RCI Bi-Flo	Proposed SOFTECH® Plus $ETCO_2$ Cannula	Performance Testing
Nasal Prongs (Nares)	Dual-channel nasal prong that allows oxygen delivery and gas sampling from both nares	Split nasal prong that directs oxygen flow into one nare and samples expired gas from the other nare	$ETCO_2$ Performance Testing with Simultaneous Oxygen Delivery
Oxygen supply tubing and CO_2 sampling line length	Oxygen supply tubing: 7 ft CO2 sampling line: 7 in	Oxygen supply tubing: 7 ft and 14 ft CO2 sampling line: 2 in, 7 ft and 14 ft	$ETCO_2$ Performance Testing with Simultaneous Oxygen Delivery
Materials			
Nares	Polyvinylchloride	Polyvinylchloride	Biocompatibility Testing: Cytotoxicity, Sensitization, Irritation, Genotoxicity, Implantation
Bolo Slide	Polycarbonate or Polyvinylchloride	Polyvinylchloride	
Tubing Clip	None	Polypropylene	
Lariat Tubing	Polyvinylchloride	Polyvinylchloride	
Oxygen Supply Tubing	Polyvinylchloride	Polyvinylchloride	
CO_2 Sampling Line	Polyvinylchloride	Polyvinylchloride	
Oxygen Connector	Polyvinylchloride	Polyvinylchloride	
Tubing Connector	Polyvinylchloride	Polyvinylchloride	
Male and Female Luer Lock Connectors	Acrylic	Polycarbonate	
22mm Oxygen	None	Polypropylene	

Tubing Adaptor			
Adhesive	Cyclohexanone	Cyclohexanone	
PVC	PVC with DEHP	Non-DEHP PVC	DEHP Testing

I. Performance Data

The proposed device was tested for $ETCO_2$ sampling at various oxygen flow rates, biocompatibility, and DEHP testing. The test results demonstrate that the device is substantially equivalent to the predicate device.

The tests performed are summarized in **Table 2** below.

Table 2 – Performance Testing Summary

General Description
$ETCO_2$ performance in simulated conditions at various oxygen flow rates
Biocompatibility testing as per ISO 10993-1: cytotoxicity, sensitization, irritation, genotoxicity and implantation testing
DEHP Testing

J. Conclusion

The device data and test results demonstrate that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2014

Teleflex Medical, Inc.
Angela Bouse
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K132946
Trade/Device Name: SOFTECH® Plus ETCO2 Cannula
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, CAT
Dated: May 02, 2014
Received: May 05, 2014

Dear Ms. Bouse:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

Erin I. Keith, M.S.
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)*
K132946

Device Name
Hudson RCI SOFTECH® Plus ETCO2 Nasal Cannula

Indications for Use *(Describe)*

The Hudson RCI SOFTECH® Plus ETCO2 Nasal Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate.

Patient Population: Infant, Pediatric, Adult

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Todd D. Courtney -S
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