DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 14, 2015

Covidien
Danielle Mueller
Regulatory Affairs Manager
6135 Gunbarrel Ave
Boulder, CO 80301

Re: K150844
Trade/Device Name: Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula
Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Reusable Inner Cannula
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: June 10, 2015
Received: June 11, 2015

Dear Ms. Mueller:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, M.S.
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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)*

K150844

Device Name
Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Reusable Inner Cannula
Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula

Indications for Use *(Describe)*

The Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Reusable Inner Cannula is intended to provide tracheal access for airway management.

The Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula is intended to provide tracheal access for airway management.

The Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Reusable Inner Cannula is also intended for use with Percutaneous Dilatational Tracheotomy (PDT) procedures.

The Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula is also intended for use with Percutaneous Dilatational Tracheotomy (PDT) procedures.

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.

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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510(k) Summary for the use of the Shiley™ Adult Flexible Tracheostomy Tube, Reusable Inner Cannula.

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	July 10, 2015
Contact Person:	Danielle Mueller Regulatory Affairs Manager (303) 305-2603
Proprietary Name:	Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Reusable Inner Cannula Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula
Common Name:	Tracheostomy Tube & Tube Cuff
Device Classification Regulation:	21 CFR 868.5800 – Class II
Device Product Code & Panel:	JOH
Predicate Devices:	Shiley™ Adult Flexible Tracheostomy Tube, Disposable Inner Cannula (K142296) Shiley™ Tracheostomy Tubes (K962173)

Device Description

The subject devices are single patient-use dual cannula tracheostomy tubes that are intended to provide an artificial airway for airway management. The subject device represents a line extension introducing the option of a reusable inner cannula.

Indications for Use/Intended Use

The Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Reusable Inner Cannula is intended to provide tracheal access for airway management.

The Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula is intended to provide tracheal access for airway management.

The Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Reusable Inner Cannula is also intended for use with percutaneous Dilatational Tracheotomy (PDT) procedures.

The Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula is also intended for use with percutaneous Dilatational Tracheotomy (PDT) procedures.

Technological Characteristics Comparison

The subject device is identical to the predicate Shiley™ Adult Flexible Tracheostomy Tube, Disposable Inner Cannula (K142296) with the exception of the inner cannula material and reuse status.

	SUBJECT	PREDICATE	
	Shiley™ Adult Flexible Tube, Reusable Inner Cannula	**Shiley™ Adult Flexible Tube, Disposable Inner Cannula [K142296]**	**Shiley™ Tracheostomy Tubes [K962173]**
Intended Use	Intended for use in providing tracheal access for airway management. Also intended for use with Percutaneous Dilatational Tracheotomy (PDT) procedures.	Identical	Intended for use in providing tracheal access for airway management in adults.
Patient Population	Adults	Identical	Identical
Environment of Use	Hospitals, long-term care facilities, home care	Identical	Identical
Use	Single patient	Identical	Identical
Inner Cannula Use	Reusable within single patient	Disposable	Reusable & disposable options available
Cuff	Cuffless or taper-shaped cuff	Identical	Cuffless or barrel-shaped cuff
Size Range	ID: 6.5mm-10.0mm OD: 9.4mm-13.8mm Length: 62mm-79mm	Identical	ID: 5.0 - 8.9mm OD: 9.4 - 13.8mm Length: 65 - 81mm
Sterilization	Ethylene Oxide	Identical	Identical
Shelf Life	2 years	Identical	5 years
MATERIALS			
Outer cannula	Medical grade PVC with citrate-based plasticizer	Identical	Medical grade PVC
Inner cannula	High density polyethylene	Low density polyethylene	*Reusable*: polycarbonate & polypropylene *Disposable*: polypropylene & PVC
Flange	Medical grade PVC with citrate-based plasticizer	Identical	Medical grade PVC
15mm Connector	Polymethylpentene	Identical	Medical grade PVC
Cuff	Medical grade PVC with DEHT-based plasticizer	Identical	Medical grade PVC
Inflation System	Medical grade PVC with citrate-based plasticizer	Identical	Medical grade PVC
Obturator	Medical grade polypropylene	Identical	Identical
Tie Strap	Cotton	Identical	Identical

Substantial Equivalence – Non-Clinical Evidence
Product performance testing, including insertion/removal force, lock & pinch force, and tests per ISO 5366-1:2009 and ISO 5361:2012 were performed with the conclusion that the subject devices can be expected to perform as well as the predicate and can be considered substantially equivalent. The cleaning methods for the reusable inner cannula were validated in accordance with AAMI TIR 30. The results from ethylene oxide residual tests on the EtO-sterilized device demonstrated compliance to ISO 10993-7:2008 for the device's intended use. Additionally, biocompatibility testing was performed per ISO 10993-1:2009 including the following: cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, subchronic toxicity implantation, chemical characterization, and risk assessment. The device met all biocompatibility requirements for its intended use.

Substantial Equivalence – Clinical Evidence
N/A – Clinical evidence was not necessary to show substantial equivalence.

Substantial Equivalence – Conclusions
No new questions of safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject devices can be considered substantially equivalent.