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

February 13, 2015

Covidien
Ms. Kelsey Lee
Regulatory Affairs Product Manager
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K142298
Trade/Device Name: Shiley™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes with TaperGuard Cuff
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube & Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: January 9, 2015
Received: January 14, 2015

Dear Ms. Lee:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
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Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142298

Device Name: Shiley™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes with TaperGuard Cuff

Indications for Use:

The Shiley™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes with TaperGuard Cuff are intended for use in providing tracheal access for airway management.

Prescription Use _____**X**_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes with TaperGuard Cuff.

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	February 12, 2015
Contact Person:	Danielle Mueller Regulatory Affairs Manager (303) 305-2603
Proprietary Name:	**Shiley™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes with TaperGuard Cuff**
Common Name:	Tracheostomy Tube & Tube Cuff
Device Classification Regulation:	21 CFR 868.5800 – Class II
Device Product Code & Panel:	JOH
Predicate Devices:	**Shiley™ Cuffed Pediatric & Pediatric Long (K955680)** **Shiley™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes Cuffless (K122531)** **Smiths Medical Bivona Aire-Cuf Tracheostomy Tubes (K083641)**

Device Description
The subject devices are single use; single cannula tracheostomy tubes that are intended to provide an artificial airway for airway management. The new features on the subject devices include a new plasticizer, the addition of the TaperGuard cuff, and additional sizes.

Indications for Use/Intended Use
The subject and predicate Shiley™ devices have identical indications and similar indications to the BIVONA Aire-Cuf device. The indications for use are as follows:
The Shiley™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes with TaperGuard Cuff are intended for use in providing tracheal access for airway management.

Technological Characteristics Comparison

The subject device only differs from the predicate Shiley™ Neonatal, Pediatric & Pediatric Long Tracheostomy Tubes Cuffless (K122531) with the addition of the cuff. They have identical indications, basic design and sizes. The subject device has a similar cuff to the predicate Shiley Cuffed Tubes (K955680) and BIVONA Tubes (K083641). The difference between the cuff on the subject and predicate tubes is the overall shape, which is taper-shaped in the subject versus barrel shaped in the predicates.

	SUBJECT DEVICE	**PREDICATE DEVICE**		
	Shiley™ Cuffed	Shiley™ Cuffed [K955680]	Shiley™ Cuffless [K122531]	BIVONA Aire-Cuf [K083641]
Indications	Intended for use in providing tracheal access for airway management.	Identical	Identical	Intended to provide direct airway access for a tracheotomized patient for up to 29 days. It may be reprocessed for a single-patient use up to 5 times for pediatric sizes.
Patient population	Neonatal & pediatric	Pediatric	Neonatal & pediatric	Neonatal & pediatric
Sterilization	EtO	EtO	EtO	EtO
Cuff shape	Taper	Barrel	N/A	Barrel
Use	Single patient use	Identical	Identical	Identical
Sizes	2.5-4.5 Neonatal 2.5-5.5 Pediatric 5.0-6.5 Pediatric long	4.0-5.5 Pediatric 5.0-6.5 Pediatric long	2.5-4.5 Neonatal 2.5-5.5 Pediatric 5.0-6.5 Pediatric long	2.5-4.0 Neonatal 2.5-5.5 Pediatric
Materials				
Cannula	Medical grade PVC with a citrate-based non-phthalate plasticizer	Medical grade PVC with a DEHP plasticizer	Medical grade PVC with a citrate-based non-phthalate plasticizer	Silicone
Flange	Medical grade PVC with a citrate-based non-phthalate plasticizer	Medical grade PVC with a DEHP plasticizer	Medical grade PVC with a citrate-based non-phthalate plasticizer	Silicone
ISO 15mm connector	Acrylonitrile butadiene styrene (ABS)	Medical grade PVC	ABS	ABS
Cuff	Medical grade PVC with a citrate-	Medical grade PVC with a DEHP	N/A	PVC

	based non-phthalate plasticizer	plasticizer		
Inflation system	Medical grade PVC with a citrate-based non-phthalate plasticizer & PVC	Medical grade PVC with a citrate-based non-phthalate plasticizer & PVC	N/A	Silicone & ABS
Obturator	Medical grade polypropylene	Medical grade polypropylene	Medical grade polypropylene	Medical grade polypropylene
Neck strap	Cotton	Cotton	Cotton	Cotton

Substantial Equivalence – Non-Clinical Evidence
Product performance testing, including cuff air seal, cuff fluid seal, removal force, and cuff pressure mapping, were performed with the conclusion that the subject devices can be expected to perform at least as well as the predicate and can be considered substantially equivalent. 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.