



COVIDIEN

510(k) Summary K122531

Date summary prepared 21-September-2012

OCT 9 2012

510(k) Submitter/Holder

Covidien llc
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Contact

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Name of Device

Trade Name: Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless
Catalog Numbers: NEF, PEF, PELF
Common Name: Tube Tracheostomy and Tube Cuff
Classification Name: JOH, Tube Tracheostomy and Tube Cuff (21 CFR 868.5800) Class II, 73-Anesthesiology

Purpose of Submission

The purpose of this submission is to introduce the Covidien Shiley Neonatal, Pediatric, Pediatric Long Cuffless Tracheostomy Tube. The subject and predicate device have the equivalent Indications for Use, Intended Use, fundamental technology, and design. This submission is to notify the FDA of the following changes:

- Pediatric and Neonatal Tracheostomy tubes size line extension of the previously cleared Shiley Pediatric and Neonatal Tracheostomy tubes
- Updated the materials used in the Tracheostomy tubes to a Medical Grade PVC with a Citric based non-phthalate plasticizer
- Update to the Manufacturing process

Predicate Device

The Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless was compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Trade Name: Shiley Pediatric and Neonatal Tracheostomy Tubes
Device Common Name: Tube Tracheostomy and Tube Cuff
510(k) Number: K945513
Manufacturer: Covidien, formerly Tyco Healthcare

Trade Name:	Bivona Tracheostomy Tube Tracheostomy Tubes
Device Common Name:	Tube Tracheostomy and Tube Cuff
510(k) Number:	K083641
Manufacturer:	Smiths Medical ASD, Inc.

Intended Use

The device is intended to be used to provide an artificial airway in order to provide access to the patient's airway for airway management. When inserted in a tracheostomy stoma, the device is secured in place with a neck strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.

Indications for Use

This device is intended for use in providing tracheal access for airway management.

Device Description

The Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless tube is a single cannula tracheostomy tube which also contains a neck strap and obturator. The device is intended to be used to provide an artificial airway in order to provide access to the patient's airway for airway management. When inserted in a tracheostomy stoma, the device may be secured in place with a neck strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.

Technological Characteristics

The Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless tube has technological characteristics that differ from its predicates. The Shiley Pediatric and Neonatal Tracheostomy Tubes (K945513) are comprised of a Medical Grade Polyvinylchloride (PVC) and BIVONA Tracheostomy Tubes (K083641) is comprised of Silicone and Acrylonitrile butadiene styrene (ABS) materials. Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless tube is comprised of a Medical Grade PVC with a Citric Based non-phthalate plasticizer. All other fundamental technological characteristics are identical to the predicate devices.

	Subject Device:	Predicate Device	Predicate Device
	Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless	Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube (K945513)	BIVONA Tracheostomy Tubes (K083641)
Indications for Use	This device is intended for use in providing tracheal access for airway management.	This device is intended for use in providing tracheal access for airway management.	The Bivona Tracheostomy Tube is 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.
Intended Use	This device is intended for use in providing tracheal access for airway management.	This device is intended for use in providing tracheal access for airway management.	Unknown
Device class	Class 2	Class 2	Class 2
Product code	JOH	JOH	JOH
Patient Population	Neonatal and Pediatric patients requiring an artificial airway	Neonatal and Pediatric patients requiring an artificial airway	Pediatric patients requiring an artificial airway
Environment of Use	The product shall be used in a clinical environment such as the neonatal, pediatric or critical care units of a hospital, non-critical care units of a hospital, long term care facilities and home care.	The product shall be used in a clinical environment such as the neonatal, pediatric or critical care units of a hospital, non-critical care units of a hospital, long term care facilities and home care.	Unknown
Invasive / Non-Invasive	Invasive	Invasive	Invasive
Sterilization	Sterile : The SAL is 10E-6 utilizing the existing validated cycle 66.	Sterile : The SAL is 10E-6 utilizing the existing validated cycle 66.	Sterile with Ethylene Oxide
Shelf Life	1-year Minimum shelf life	5-year shelf life	Unknown
Materials			

	Subject Device:	Predicate Device	Predicate Device
	Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless	Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube (K945513)	BIVONA Tracheostomy Tubes (K083641)
Cannula	Medical Grade PVC with a Citric Based non- phthalate plasticizer	Medical Grade PVC	Silicone
Neck Plate	Medical Grade PVC with a Citric Based non- phthalate plasticizer	Medical Grade PVC	Silicone
15 MM connector	Medical Grade PVC with a Citric Based non- phthalate plasticizer	Medical Grade PVC	Acrylonitrile butadiene styrene (ABS)
Obturator	Medical Grade Polypropylene	Medical Grade Polypropylene	Medical Grade Polypropylene
Tie Strap	Cotton	Cotton	Cotton
Biocompatibility	ISO 10993-1:2009	ISO 10993-1:2009	ISO 10993-1:2009
Sizes	2.5 NEF to 4.5 NEF 2.5 PEF to 5.5 PEF 5.0 PELF to 6.5 PELF	3.0 NEO to 4.5 NEO 3.0 PED to 5.5 PED 5.0 PDL to 6.5 PDL	2.5 to 4.0 Neonatal 2.5 to 5.5 Pediatric
Use	Single Patient Use	Single Patient Use	Single Patient Use
Design	Tracheostomy Tube Design	Tracheostomy Tube Design	Tracheostomy Tube Design

	Subject Device:	Predicate Device	Predicate Device
	Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless	Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube (K945513)	BIVONA Tracheostomy Tubes (K083641)
Standards met	<p>ISO 5366-1:2000 Anesthetic and respiratory equipment — Tracheostomy tubes Part 1: Tubes and connectors for use in adults</p> <p>ISO 5366-3:2001 / Cor:2003 Anesthetic and Respiratory Equipment -- Tracheostomy Tubes -- Part 3: Pediatric Tracheostomy Tubes</p> <p>ISO 5356-1:2004 Anesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets</p> <p>(The key product standards used to develop this product range are ISO 5366 Part 3 and ISO 5356-1. The PDL model encompasses a 6.5mm Tracheostomy tube. The 6.5mm tube is beyond the scope of ISO 5366 Part 3. Therefore ISO 5366 Part 1 is also used to guide the development of the product range)</p>	<p>5356 (1987) 5366 (1985)</p>	<p>ISO 5366-3:2001</p> <p>ISO 5366-3:2001 Second edition 2001- 08-15</p> <p>ISO 5356-1 Third edition 2004-05-15</p>

Non-Clinical Data

Bench testing was performed to confirm that the Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless meets the requirements of ISO 5366-3 [2001/Cor:2003], ISO 5356-1:2004 and ISO 5366-1:2000 for Tracheostomy Tubes. Biocompatibility testing was performed on the Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless which satisfied all of the requirements of ISO 10993-1:2009.

Clinical Data

Not Required

Substantial Equivalence

The predicate devices to which we claim equivalence are the Shiley Pediatric and Neonatal Tracheostomy Tubes (K945513) and BIVONA Tracheostomy Tubes (K083641). The basic design elements and their assemblies are identical to the cleared predicate device. The Indications for Use of the proposed devices are equivalent to the cleared predicate devices.



Food and Drug Administration
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OCT 9 2012

Re: K122531

Trade/Device Name: Shiley Neonatal Tracheostomy Tube Cuffless
Shiley Pediatric Tracheostomy Tube Cuffless
Shiley Pediatric Tracheostomy Tube Long Cuffless

Regulation Number: 21 CFR 686.5800

Regulation Name: Tracheostomy Tube and Tube Cuff

Regulatory Class: II

Product Code: JOH

Dated: September 21, 2012

Received: September 24, 2012

Dear Mr. Kuhn:

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 go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122531

Device Name:

Shiley Neonatal Tracheostomy Tube Cuffless
Shiley Pediatric Tracheostomy Tube Cuffless
Shiley Pediatric Tracheostomy Tube Long Cuffless

Indications for Use:

This device is 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)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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