May 20, 2024

Covidien LLC
Stephanie Reneau
Principal Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K233341
Trade/Device Name: Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non-DEHP (87430, 87435, 87440, 87445, 87450, 87455, 87460, 87465, 87470, 87475, 87480, 87485, 87490, 87495, 87410)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: April 12, 2024
Received: April 12, 2024

Dear Stephanie Reneau:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and

Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233341

Device Name

Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non-DEHP (87430, 87435, 87440, 87445, 87450, 87455, 87460, 87465, 87470, 87475, 87480, 87485, 87490, 87495, 87410)

Indications for Use *(Describe)*

Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non-DEHP is intended for oral or nasal intubation of the trachea.

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.

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510(K) SUMMARY

Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP

This summary of 510(k) safety and effectiveness information for the Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non-DEHP is submitted in accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with the requirements of 21 CFR §807.92.

SUBMITTER INFORMATION

Submitted By:
Covidien, llc
6135 Gunbarrel Avenue
Boulder, CO 80301

Establishment Registration Number: 2936999

Date Prepared: 05/14/2024

Contact Person:

Stephanie Reneau

Principal Regulatory Affairs Specialist

Phone: 303-305-2713

Email : stephanie.reneau@medtronic.com

DEVICE

Trade Name: Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP

Common Name: Endotracheal Tube with Cuff

Classification Regulation: 21 CFR § 868.5730

Classification Name: Tube, Tracheal (w/wo connector)

Regulatory Class: Class II

Product Code: BTR

Review Panel: Anesthesiology

PREDICATE DEVICE

Predicate Manufacturer: Covidien llc

Predicate Trade Name: Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non-DEHP

Predicate 510(k): K223130

DEVICE DESCRIPTION

The subject device is an oral/nasal endotracheal tube intermediate cuff. The translucent tube incorporates a Magill curve and features a radiopaque line. The tube features a thin wall, polyvinyl chloride (PVC) high pressure, low volume cuff with two different cuff shapes. An inflation system consisting of an inflation line, pilot balloon, and inflation valve allows inflation and deflation of the cuff. The subject device is manufactured from materials without latex or DEHP.

INTENDED USE

The Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP is intended for use in oral or nasal intubation of the trachea for anesthesia and is indicated for airway management.

TECHNOLOGICAL CHARACTERISTICS

The subject device is substantially equivalent to the predicate device in terms of technological characteristics. Both devices are designed in accordance with ISO 5361 and have the following features in common: standard 15mm connector, Magill curve, similar material composition, and similar size range. The following technological characteristics were compared between the subject device, predicate devices, and reference device to demonstrate substantial equivalence in **Table 1** below:

Table 1. *Comparison of Technological Characteristics*

Characteristics	**Subject Device:** Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non-DEHP	**Predicate Device:** Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, non-DEHP (K223130)	**Reference Device** Shiley™ Hi-Lo Oral/Nasal Tracheal Tube Cuffed, Intermediate, Murphy Eye (K965132)	**Reference Device** Cuffed Tracheal Tube (Multiple) (K871204)
Indications for Use	Oral or nasal intubation of the trachea for airway management.	Oral or nasal intubation of the trachea for airway management.	Intubation of trachea for airway management	Intubation of trachea for airway management
Patient Population	Pediatric and Adults	Pediatric	Pediatric and Adults	Pediatric and Adults
Use	Single Patient Use	Single Patient Use	Single Patient Use	Single Patient Use
Product Size Range (nominal inside diameter)	3.0-10.0 mm	2.5-6.0 mm	3.0 to 10.0 mm	5.0 to 10.0 mm
Shelf Life	5 years	5 years	5 years	5 years
Sterilization	Ethylene Oxide (SAL) of 10^{-6}	Ethylene Oxide (SAL) of 10^{-6}	Ethylene Oxide (SAL) of 10^{-6}	Ethylene Oxide (SAL) of 10^{-6}
MRI Compatibility	MRI Conditional	MRI Conditional	MRI Conditional	MRI Conditional

SUBSTANTIAL EQUIVALENCE DISCUSSION

Indications for Use

The subject device and predicate device share the same intended use, both devices provide tracheal access for airway management. The subject and predicate devices are indicated for facilitating oral or nasal intubation of the trachea.

The Shiley™ Oral/Nasal Endotracheal Intermediate Cuff, Non DEHP is designed with a high volume, low pressure cuff which comes in two cuff shapes based on tube size to provide air and fluid seal. Additionally, the subject device uses the same materials used in the predicate device.

Technical Characteristics Comparison

The subject and predicate devices have the same technological characteristics (Magill curve, 15 mm connector, inflation system, similar size range and material composition). The subject device was tested to comply with FDA recognized standards related to airway devices, ISO 5361, ISO 5356 and ISO 18190 (see Declaration of Conformity section).

The subject device can be considered substantially equivalent to the predicate device as they both have the same intended use, designed in accordance with ISO 5361 and ISO 5356 requirements.

PERFORMANCE DATA

Performance bench testing has been conducted to verify the performance of the subject device the Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP will perform as intended and is substantially equivalent to the predicate device. Bench top testing has been conducted on the subject device per ISO 5361:2016 (FDA 1-118) and all testing requirements were met. The following tests were performed on terminally sterilized samples which met all defined acceptance criteria:

- Connector Pull Test
- Cuff Performance
- Inflation Line Pull Test
- Fluid Seal Test
- Kink Resistance
- Print Adherence

The Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP met the standard supporting a 5-year shelf life.

The Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP has been tested in accordance with the standard ISO 5361:2016 for dimensions, bevel angle, radius of curvature, cuff diameter, connectors and met the standard. The subject device was compared to the predicate device and considered substantially equivalent as the device met the same acceptance criteria as the predicate device.

BIOCOMPATIBILITY TESTING

- The following biocompatibility testing was performed in accordance with ISO 10993-1:2018 (FDA 2-258). The subject device has two different resins, one for sizes 3.0 to 8.0 mm and second for sizes 8.5 to 10.0 mm. Testing from predicate device was leveraged for sizes 3.0-8.0 mm and for sizes 8.5 mm to 10.0 mm, testing was performed on final finished subject device.
- Cytotoxicity
- Implantation
- Sensitization
- Irritation/Intracutaneous reactivity
- Material Mediated Pyrogenicity

HUMAN FACTORS

The Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP was evaluated for human factors/usability study and found to be in conformance with EN 62366-1:2015 + A1:2020 Medical devices- Application of usability engineering medical devices standard.

STERILIZATION

Sterilization by ethylene oxide has been validated for Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP.

ANIMAL PERFORMANCE TESTING

Not applicable. Non animal performance testing was required to demonstrate the device's safety and effectiveness.

CLINICAL PERFORMANCE TESTING

Not applicable. Non animal performance testing was required to demonstrate the device's safety and effectiveness.

CONCLUSION

Based on the information included in this premarket notification submission, the Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP met all predetermined acceptance criteria as specified in the applicable standards, test protocols and FDA guidance documents. Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP is considered substantially equivalent to Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, non-DEHP, predicate device and reference devices Shiley™ Hi-Lo Oral/Nasal Tracheal Tube Cuffed, Intermediate, Murphy Eye (K965132) and Cuffed Tracheal Tube, Multiple (K871204) currently marketed for the same intended use.