August 30, 2023

Covidien
Anila Tarte
Principal Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K223130
Trade/Device Name: Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP (86125, 86130, 86135, 86140, 86145, 86150, 86155, 86160)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: Class II
Product Code: BTR
Dated: June 27, 2023
Received: June 27, 2023

Dear Anila Tarte:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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)*

K223130

Device Name

Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP (86125, 86130, 86135, 86140, 86145, 86150, 86155, 86160)

Indications for Use *(Describe)*

The Shiley™ pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non DEHP is intended for use in facilitating 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™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP

This summary of 510(k) safety and effectiveness information for the Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ 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:** June 25, 2023

**Contact Person:**
Anila Tarte
Principal Regulatory Affairs Specialist
Phone: 978-496-6694
Email: anila.k.tarte@medtronic.com

### DEVICE

| | |
|---|---|
| Trade Name: | Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non-DEHP (86125, 86130, 86135, 86140, 86145, 86150, 86155, 86160) |
| Common Name: | Endotracheal Tube with cuff |
| Classification Regulation: | 21 CFR 868.5730 |
| Classification Name: | Tracheal tube – Class II |
| Regulatory Class: | Class II |
| Product Code: | BTR |
| Review Panel: | Anesthesiology |

**PREDICATE DEVICE**

| | |
|---|---|
| Predicate Manufacturer: | Covidien llc |
| Predicate Trade Name: | Mallinckrodt™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye |
| Predicate 510(k): | K151381 |

**PREDICATE DEVICE**

| | |
|---|---|
| Predicate Manufacturer: | Covidien llc |
| Predicate Trade Name: | Hi-Lo Evac and Evac II Endotracheal Tubes |
| Predicate 510(k): | K965132 |

**REFERENCE DEVICE**

| | |
|---|---|
| Predicate Manufacturer: | Covidien llc |
| Predicate Trade Name: | Shiley™ Neonatal/Pediatric Tracheostomy Tube |
| Predicate 510(k): | K182861 |

**DEVICE DESCRIPTION**

The subject device is pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff. The translucent tube incorporates a Magill curve and features a radiopaque line. The tube features a thin wall, polyvinyl chloride (PVC) low pressure taper-shaped cuff (TaperGuard™) to provide air and fluid seal. 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™ pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non DEHP is intended for use in facilitating oral or nasal intubation of the trachea.

**TECHNOLOGICAL CHARACTERISTICS**

The subject device is substantially equivalent to the predicate devices in terms of technological characteristics. Both devices are designed in accordance with ISO 5361 and have the following features in common: Cuff, standard 15mm connector, Magill curve, similar material composition, and similar size range. The following technological characteristics were compared between the subject device and predicate devices to demonstrate substantial equivalence in **Table 5.1** below:

***Table 5.1**: Comparison of Technological Characteristics*

| **Characteristic** | **Subject Device** Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP | **Primary Predicate Device** Mallinckrodt™ Oral/Nasal Tracheal Tube Cuffless, Non- DEHP-, Murphy Eye [K151381] | **Secondary Predicate device** Hi-Lo Evac and Evac II Endotracheal Tubes (K965132) |
|---|---|---|---|
| Indications for Use | Oral or nasal intubation of the trachea for airway management. | Oral or nasal intubation of the trachea for airway management. | The Hi-Lo- Evac™ endotracheal tube is indicated for airway management by oral/nasal intubation of the trachea particularly in cases where duration of intubation is expected to be more than 24 hours or may not be predictable. |
| **Patient Population** | Pediatrics | Pediatrics | Pediatrics, Adults |
| Use | Single patient | Single patient | Single patient |
| Device Design | Per ISO 5361:2016, ISO 5356-1 | Per ISO 5361:2012, ISO 5356-1 | Per ISO 5361:1999, ISO 5356-1 |
| Product Size range (nominal inside diameter) | 2.5-6.0mm | 2.0 – 7.0mm | 3.0 – 10.0mm |
| Shelf life | 5 years | 5 years | 5 years |
| Sterilization | SAL: 1X10-6 ETO Sterilization | SAL: 1X10-6 ETO Sterilization | SAL: 1X10-6 ETO Sterilization |

## Substantial Equivalence Discussion

### Indications for Use

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

The Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP is designed with a low-pressure taper-shaped cuff (TaperGuard™) to provide air and fluid seal.

Additionally, the subject device tube and cuff uses identical materials used in the primary device and reference device respectively.

**Technological Characteristics Comparison**

The subject and predicate devices have the same technological characteristics (Magill curve, similar size range, similar material composition, cuff, inflation line, 15 mm connector).

The subject device was tested to comply with FDA recognized standards related to Airway devices, ISO 18190, ISO 5361 and ISO 5356 (see Section Declaration of Conformity).

As the subject and predicate devices have the same intended use, designed in accordance with ISO 5361, and performance in compliance with ISO 5361 requirements, the subject device can be considered substantially equivalent to the predicate device.

**PERFORMANCE DATA**

Performance Bench Testing has been conducted to verify that the performance of the subject device the Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP is substantially equivalent to the predicate devices and that the subject device will perform as intended. Bench-top testing have been conducted on subject device in accordance with ISO 5361:2016 and all testing requirements were met. The following tests were performed on terminally sterilized unaged and aged samples which met all defined acceptance criteria:

- Print Adherence Test
- Cuff herniation
- Cuff performance
- Inflation line pull test
- Connector pull force
- Kink test
- Tube collapse
- Fluid Seal test
- Radius Curvature test
- MRI Safety and compatibility tests

The Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP unaged and aged met the standard, supporting the 5-year shelf life.

The Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP has been tested in accordance with the standard ISO 5361:2016 for dimensions, including bevel angle, curvature, cuff diameter, connectors. The subject device met the standard.

The Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP was

compared to the predicate device for the functional and mechanical tests and met the same acceptance criteria as the predicate device, demonstrating substantial equivalence.

**Biocompatibility Testing**

The following Biocompatibility testing was performed in accordance with ISO 10993-1:2009 and FDA guidance on Use of International Standard ISO 10993-1

- Cytotoxicity
- Implantation
- Sensitization
- Irritation / Intracutaneous reactivity
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Subacute/sub chronic toxicity
- Genotoxicity
- Particulate matter and VOC (ISO 18562-2:2017 & ISO 18562-3:2017)

**Human Factors**

A Human Factors / Usability Study was conducted and the Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP was found to be in conformance with the IEC 62366-1:2015 Medical devices – Application of usability engineering to medical devices standard.

**Sterilization**

Sterilization by ethylene oxide has been validated for Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP.

**Animal Performance Testing**

Not applicable. No animal performance testing was required to demonstrate device safety and effectiveness.

**Clinical Performance Testing**

No clinical performance testing was required to demonstrate device safety and effectiveness.

## CONCLUSION

Based on the information included in this premarket notification submission, the Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP met all predetermined

acceptance criteria as specified by the applicable standards, FDA guidance documents and test protocols. Therefore, the Shiley™ Pediatric oral/nasal endotracheal tube with TaperGuard™ Cuff, non-DEHP is considered substantially equivalent to the predicate devices currently marketed for the same intended use.