September 25, 2025

Covidien LLC
Shruti Shah
Principal Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K243785
Trade/Device Name: Shiley™ Oral/Nasal Tracheal Tube with TaperGuard™ Cuff Reinforced, Murphy Eye Shiley™ Tracheal Tube TaperGuard™ Cuff Reinforced with Stylet Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye Shiley™ Oral/Nasal Tracheal Tube Cuffless Reinforced
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: September 16, 2025
Received: September 16, 2025

Dear Shruti Shah:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243785

Device Name
Shiley™ Oral/Nasal Tracheal Tube with TaperGuard™ Cuff Reinforced, Murphy Eye; Shiley™ Tracheal Tube TaperGuard™ Cuff Reinforced with Stylet; Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced; Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye; Shiley™ Oral/Nasal Tracheal Tube Cuffless Reinforced

Indications for Use *(Describe)*
These devices are intended for oral or nasal intubation and are indicated for use in airway management, including those procedures requiring flexing of the neck or movement of the patient (e.g., to a lateral or prone position).

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

This summary of 510(k) safety and effectiveness information for the Shiley™ Reinforced Tracheal Tubes 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.

I. SUBMITTER INFORMATION

Submitted By:	Covidien LLC 6135 Gunbarrel Avenue, Boulder, CO 80301
Establishment Registration Number:	2936999
Contact Person:	Shruti Shah Principal Regulatory Affairs Specialist Phone: (720) 980-5191 Email: shruti.shah@medtronic.com
Date:	December 09, 2024

II. DEVICE

Trade or Proprietary Name:	a) Shiley™ Oral/Nasal Tracheal Tube with TaperGuard™ Cuff Reinforced, Murphy Eye b) Shiley™ Tracheal Tube TaperGuard™ Cuff Reinforced with Stylet c) Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced d) Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye e) Shiley™ Oral/Nasal Tracheal Tube Cuffless Reinforced
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

III. PREDICATE & REFERENCE DEVICES

Predicate Device:

Predicate Manufacturer: Covidien LLC
Predicate Trade Name: Shiley™ Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye (Armored Tracheal Tube)

Predicate 510(k): K790575

Reference Devices:

Product Family	Reference Devices
Shiley™ Oral/Nasal Tracheal Tube with TaperGuard™ Cuff Reinforced, Murphy Eye	Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula (K142296)
Shiley™ Tracheal Tube TaperGuard™ Cuff Reinforced with Stylet	
Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced	Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP (K233341)
Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye	
Shiley™ Oral/Nasal Tracheal Tube Cuffless Reinforced	Mallinckrodt™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye (K151381)

IV. DEVICE DESCRIPTION

The subject devices are sterile, single-use tracheal tubes that incorporate a pre-formed Magill curve and have a continuous stainless-steel spiral wire incorporated into the wall to reduce the risk of collapse or kinking during patient positioning. All tracheal tubes feature standard depth marks, glottic depth marks and 15mm connector. The cuffed devices are provided with two different low-pressure cuff types, featuring a thin compliant wall that, when inflated, adapts and conforms to the irregular borders of the tracheal wall. The cuffed devices have an inflation system consisting of an inflation line, pilot balloon and self-sealing inflation valve, allowing for inflation and deflation of the cuff.

Five families of the subject devices share the same indications for use and intended use but differ in specific design features such as size, cuff presence, cuff shape, presence of murphy eye and stylet.

V. INTENDED USE

Product Family	Intended Use
Shiley™ Oral/Nasal Tracheal Tube with TaperGuard™ Cuff Reinforced, Murphy Eye (118-xxMTG)	Shiley™ Oral/Nasal Tracheal Tube with TaperGuard™ Cuff Reinforced, Murphy Eye are intended for *oral or nasal* intubation of the trachea.
Shiley™ Tracheal Tube TaperGuard™ Cuff Reinforced with Stylet (118-xxTGS)	Shiley™ Tracheal Tube with TaperGuard™ Cuff Reinforced with Stylet are intended for *oral* intubation of the trachea.
Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced (118-xx)	Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced are intended for *oral or nasal* intubation of the trachea.
Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye (118-xxM)	Shiley™ Lo-Contour Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye are intended for *oral or nasal* intubation of the trachea.
Shiley™ Oral/Nasal Tracheal Tube Cuffless Reinforced (127-XX-2)	Shiley™ Oral/Nasal Tracheal Tube Cuffless Reinforced are intended for *oral or nasal* intubation of the trachea.

VI. INDICATIONS FOR USE

These devices are intended for oral or nasal intubation and are indicated for use in airway management, including those procedures requiring flexing of the neck or movement of the patient (e.g., to a lateral or prone position).

VII. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject devices are substantially equivalent to the predicate devices (K790575) . They share same intended use, indications for use and certain technological characteristics. The following technological characteristics were compared between the subject, predicate and reference devices to demonstrate substantial equivalence:

	Subject Device	**Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**
	Shiley™ Reinforced Tracheal Tubes (118-xxMTG, 118-xxTGS, 118-xx, 118-xxM, 127-xx-2)	**Shiley™ Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye (K790575)**	**Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula (K142296)**	**Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP (K233341)**	**Mallinckrodt ™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye (K151381)**
Indications for Use	intended for oral or nasal intubation and is indicated for use in airway management, including those procedures requiring flexing of the neck or movement of the	intended for nasal/oral intubation and is indicated for use in airway management, including those procedures	intended for use in providing tracheal access for airway management and intended for use with Cook® Percutaneous	intended for Oral or nasal intubation of the trachea for airway management.	intended for Oral or nasal intubation of the trachea for airway management.

	Subject Device	Predicate Device	Reference Device	Reference Device	Reference Device
	Shiley™ Reinforced Tracheal Tubes (118-xxMTG, 118-xxTGS, 118-xx, 118-xxM, 127-xx-2)	**Shiley™ Oral/Nasal Tracheal Tube Cuffed Reinforced, Murphy Eye (K790575)**	**Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula (K142296)**	**Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP (K233341)**	**Mallinckrodt ™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye (K151381)**
	patient (e.g., to a lateral or prone position).	requiring flexing of the neck.	Dilatational Tracheotomy (PDT) procedures.		
Patient Population	Adult and/or Pediatric	Adult	Adult	Adult and Pediatric	Pediatric
Use	Single Patient	Single Patient	Single Patient	Single Patient	Single Patient
Device Design	ISO 5361 ISO 5356-1	ISO 5361	ISO 5366 ISO 5356-1 ISO 5361	ISO 5361 ISO 5356-1	ISO 5361 ISO 5356-1
Tube design	Stainless-steel spiral wire embedded between two layers of PVC	Stainless-steel spiral wire embedded between two layers of PVC	N/A	N/A	N/A
Cuff design	Low-pressure cuff or Cuffless	Low-pressure cuff	Low-pressure cuff	Low-pressure cuff	Cuffless
Connector	Standard 15mm connector	Standard 15mm connector	Standard 15mm connector	Standard 15mm connector	Standard 15mm connector
Size range	118-xxMTG: 6.0mm-9.5mm, 118-xxTGS: 6.0mm-9.0mm, 118-xx: 3.0mm - 9.5mm, 118-xxM: 6.0mm - 9.5mm 127-xx-2: 3.0mm- 7.0mm	6.0mm- 9.5mm	6.5mm -10.0mm	3.0mm-10.0mm	2.0mm - 7.0mm
Shelf life	5-years	5-years	5-years	5-years	5-years
Materials	Non-DEHP PVC	PVC	Non-DEHP PVC	Non-DEHP PVC	Non-DEHP PVC
Sterilization	Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6})
MRI Compatibility	MR Unsafe	MR Unsafe	MRI Conditional	MRI Conditional	MR Safe

Substantial Equivalence Discussion:

Indications for Use:

The subject and predicate devices have the same indications for use. Both are intended for oral or nasal intubation and are indicated for use in airway management, including those procedures requiring flexing of the neck or movement of the patient.

Technological Characteristics:

The subject and predicate devices have the same technological characteristics: Magill curve, 15 mm connector, similar size range (118-xxMTG, 118-xxTGS, 118-xxM), stainless-steel spiral wire in tube, tube marking, presence of murphy eye (118-xxMTG, 118-xxTGS, 118-xxM), inflation system (for cuffed devices), hi- volume low-pressure cuff (118-xx, 118-xxM).

The subject and reference devices have the same technological characteristics: 15 mm connector, similar size range (118-xx, 127-xx-2) , inflation system (for cuffed devices), non-DEHP PVC materials, low-pressure taper shaped cuff (118-xxMTG, 118-xxTGS).

The subject, predicate and reference devices were tested to comply with FDA recognized standards for airway devices, ISO 5361 and ISO 5356-1.

To conclude, the subject device and legally marketed predicate devices (K790575) share the same intended use, indications for use, reinforced tube design and other design features like tube marking, murphy eye, inflation system and presence of cuff. Additionally, reference devices (K142296, K233341, K151381) with same intended use and similar technological characteristics further strengthen the safety and performance related to the use of non-DEHP PVC as well as the subject device's cuff shape and additional size ranges.

While the subject device differs from the predicate device in certain technological characteristics, these differences do not raise different questions regarding the subject device's safety or effectiveness.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance Testing:

Performance testing has been conducted to verify that the subject devices perform as intended. Testing was carried out according to the recognized consensus standard (ISO 5361 and ISO 5356-1), as well as internally developed test methods and acceptance criteria, to support substantial equivalence to the predicate and reference devices.

The subject device has successfully met all required standard testing in accordance with ISO 5361 and ISO 5356-1, including visual inspection, dimensional verification, bevel angle, cuff inflation and deflation, kink resistance, radius of curvature and connector strength.

In addition to above testing, the internally developed test methods were performed on terminally sterilized samples which met all defined acceptance criteria.

The subject device packaging provides adequate protection by maintaining sterile integrity of the sterile barrier system (SBS) through the possible effects of aging and environmental conditions.

The stability and shelf-life testing demonstrate that the subject devices maintain their intended functionality and packaging sterile barrier integrity, meeting all required standards for a 5-year shelf life.

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

- Cytotoxicity
- Sensitization
- Irritation
- Material Mediated Pyrogenicity
- Acute systemic toxicity
- Sub-acute toxicity
- Implantation
- Chemical characterization
- Toxicological risk assessment

Additionally, the subject device has indirect contact with the patient through the gas pathway and was evaluated for particulate matter (PM) and volatile organic compounds (VOCs) per ISO 18562-1.

Human Factors Evaluation:
A Human Factors assessment was conducted and Shiley™ Reinforced Tracheal Tubes were found to be in conformance with EN 62366-1:2015+A1:2020 and IEC 62366-1:2015 + A1:2020.

Sterilization:
The subject devices are sterilized by ethylene oxide (EO) sterilization method. They are not intended to be reprocessed or sterilized by the end user. The EO sterilization effectively sterilizes the subject devices to a sterility assurance level (SAL) of 10^{-6}.

Animal Performance Testing:
No animal performance testing was required to demonstrate subject device safety and effectiveness.

Clinical Performance Testing:
No clinical performance testing was required to demonstrate subject device safety and effectiveness.

IX. CONCLUSION

Based on the information provided in this premarket notification submission, including device comparisons, performance testing, and intended use, the Shiley™ Reinforced Tracheal Tubes meets applicable safety and performance standards and perform as intended in a manner identical to the predicate. The different technological characteristics do not raise different questions of safety or effectiveness. Therefore, Shiley™ Reinforced Tracheal Tubes are considered substantially equivalent to the predicate devices currently marketed for the same intended use.