December 29, 2025

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

Re: K251313
Trade/Device Name: Shiley™ Adult Flexible Tracheostomy Tube XLT with TaperGuard™ Cuff, Distal with Disposable Inner Cannula; Shiley™ Adult Flexible Tracheostomy Tube XLT with TaperGuard™ Cuff, Proximal with Disposable Inner Cannula; Shiley™ Adult Flexible Tracheostomy Tube XLT Cuffless, Distal with Disposable Inner Cannula ; Shiley™ Adult Flexible Tracheostomy Tube XLT Cuffless, Proximal with Disposable Inner Cannula; Shiley™ Adult Flexible Disposable Inner Cannula XLT
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube And Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: December 5, 2025
Received: December 5, 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,

JAMES J. LEE -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251313

Please provide the device trade name(s).

Shiley™ Adult Flexible Tracheostomy Tube XLT with TaperGuard™ Cuff, Distal with Disposable Inner Cannula;
Shiley™ Adult Flexible Tracheostomy Tube XLT with TaperGuard™ Cuff, Proximal with Disposable Inner Cannula;
Shiley™ Adult Flexible Tracheostomy Tube XLT Cuffless, Distal with Disposable Inner Cannula ;
Shiley™ Adult Flexible Tracheostomy Tube XLT Cuffless, Proximal with Disposable Inner Cannula;
Shiley™ Adult Flexible Disposable Inner Cannula XLT

Please provide your Indications for Use below.

These devices are intended for use in providing tracheal access for airway management.
These devices are also intended for use with percutaneous dilatational tracheotomy (PDT) procedures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information for the Shiley™ Adult Flexible Tracheostomy Tube XLT with Disposable Inner Cannula 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 200 Medtronic Dr Lafayette, CO 80026
Establishment Registration Number:	2936999
Contact Person:	Shruti Shah, Principal Regulatory Affairs Specialist Phone: (720) 980-5191 Email: shruti.shah@medtronic.com
Date:	April 28, 2025

II. DEVICE

Trade or Proprietary Name:	a) Shiley™ Adult Flexible Tracheostomy Tube XLT with *TaperGuard™ Cuff, Distal* with Disposable Inner Cannula (xxFXLTCD) b) Shiley™ Adult Flexible Tracheostomy Tube XLT with *TaperGuard™ Cuff, Proximal* with Disposable Inner Cannula (xxFXLTCP) c) Shiley™ Adult Flexible Tracheostomy Tube XLT *Cuffless, Distal* with Disposable Inner Cannula (xxFXLTUD) d) Shiley™ Adult Flexible Tracheostomy Tube XLT *Cuffless, Proximal* with Disposable Inner Cannula (xxFXLTUP) e) Shiley™ Adult Flexible Disposable Inner Cannula XLT (xxFXLTIN)
Common Name:	Tube Tracheostomy and Tube Cuff
Regulation Number:	21 CFR § 868.5800
Classification Name:	Tube Tracheostomy and Tube Cuff
Regulatory Class:	Class 2
Product Code:	JOH
Review Panel:	Anesthesiology

III. PREDICATE & REFERENCE DEVICES

Predicate Device:

Predicate Manufacturer: Covidien LLC
Predicate Device Name: Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula; Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff™, Disposable Inner Cannula
Predicate 510(k): K142296

Reference Devices:

1. **Reference 1 Manufacturer:** Covidien LLC*
   Device Name: Shiley™ Tracheosoft XLT Extended Length Tracheostomy Tube and Inner Cannula
   510(k): K051416

2. **Reference 2 Manufacturer:** Covidien LLC
   Device Name: Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Reusable Inner Cannula, Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Reusable Inner Cannula
   510(k): K150844

*The legacy XLT (K051416) was originally cleared under the name "Shiley™ TracheoSoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula" by Mallinckrodt Medical Inc. Tyco Healthcare bought Mallinckrodt Medical, Inc in 2000 and spun off its healthcare business into Covidien LLC in 2007. Following the separation, Covidien LLC initiated rebranding activities in 2011, during that period, the legacy XLT (K051416) was renamed to "Shiley™ Tracheostomy Tube XLT cuffed or cuffless, with Disposable Inner Cannula (Distal/ Proximal)". Later, Medtronic acquired Covidien in 2015 but retained the existing product names.

IV. DEVICE DESCRIPTION

The subject devices are sterile, single use dual cannula tracheostomy tube that has 90° curve and biocompatible radiopaque outer cannula with a distal or proximal extension (XLT) designed for patients with challenging anatomy.

All tracheostomy tubes feature flexible disposable inner cannula with full circumference at proximal end and a flexible laser-etched flange with integrated standard 15mm connector. The cuffed devices are provided with low-pressure TaperGuard™ cuff, 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.

The subject devices are manufactured from medical grade polyvinyl chloride (PVC) with non-Di(2-ethylhexyl) phthalate (DEHP) plasticizer and are sterilized by ethylene oxide (EO) sterilization method.

The cuffed and cuffless configurations of subject devices with distal and proximal extensions are available in four (4) sizes from 5.0mm to 8.0mm.

All four configurations and sizes of the subject devices share the same intended use and indications but differ in specific design features such as presence of low-pressure TaperGuard™ cuff and distal/ proximal extension configuration.

V. INTENDED USE

The subject devices provide tracheal access for airway management.

VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject devices are substantially equivalent to the predicate devices (K142296). They share same intended 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 1	Reference Device 2
	Shiley™ Adult Flexible Tracheostomy Tube XLT, with Disposable Inner Cannula (xxFXLTCD, xxFXLTCP, xxFXLTUD, xxFXLTUP, xxFXLTIN)	**Shiley™ Adult Flexible Tracheostomy Tube with or without TaperGuard™ Cuff, Disposable Inner Cannula (K142296)**	**Shiley TracheoSoft™ XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula (K051416)**	**Shiley™ Adult Flexible Tracheostomy Tube with or without TaperGuard™ Cuff, Reusable Inner Cannula (K150844)**
Indications for Use	The subject device is intended for use in providing tracheal access for airway management. The device is also intended for use with percutaneous dilatational tracheotomy (PDT) procedures.	The device is intended for use in providing tracheal access for airway management. The device is also intended for use with Cook® Percutaneous Dilatational Tracheotomy (PDT) procedures.	The device is intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff is intended to establish a seal between the tracheal wall and the tracheostomy tube. The device is intended to be a component of a life-sustaining device to be used with adult patients	The device is intended provide tracheal access for airway management. The device is also intended for use with percutaneous dilatational tracheotomy (PDT) procedures.
Product Code	JOH	JOH	JOH	JOH
Regulation Number	21 CFR § 868.5800	21 CFR § 868.5800	21 CFR § 868.5800	21 CFR § 868.5800
Patient Population	Adult	Adult	Adult	Adult

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
	Shiley™ Adult Flexible Tracheostomy Tube XLT, with Disposable Inner Cannula (xxFXLTCD, xxFXLTCP, xxFXLTUD, xxFXLTUP, xxFXLTIN)	**Shiley™ Adult Flexible Tracheostomy Tube with or without TaperGuard™ Cuff, Disposable Inner Cannula (K142296)**	**Shiley TracheoSoft™ XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula (K051416)**	**Shiley™ Adult Flexible Tracheostomy Tube with or without TaperGuard™ Cuff, Reusable Inner Cannula (K150844)**
Use	Single Patient	Single Patient	Single Patient	Single Patient
Use Environment	Hospital environments, long-term care facilities, Home care use	Hospital environments, long-term care facilities, Home care use	Hospital environments, Home care use	Hospital environments, long-term care facilities, Home care use
Device Design	ISO 5366 ISO 5356-1	ISO 5366 ISO 5356-1	ISO 5366 ISO 5356-1	ISO 5366 ISO 5356-1
Size range	5.0mm to 8.0mm	6.5mm to 10.0mm	5.0mm to 8.0mm	6.5mm to 10.0mm
Shelf life	5-years	5-years	5-years	5-years
Configurations	1. Cuffed with Distal extension 2. Cuffless with Distal extension 3. Cuffed with Proximal extension 4. Cuffless with Proximal extension	1. Cuffed 2. Cuffless	1. Cuffed with Distal extension 2. Cuffless with Distal extension 3. Cuffed with Proximal extension 4. Cuffless with Proximal extension	1. Cuffed 2. Cuffless
Cuff design if applicable	Low-pressure TaperGuard™ cuff	Low-pressure TaperGuard™ cuff	High-volume, low-pressure cuff	Low-pressure TaperGuard™ cuff
Connector	Standard 15mm connector	Standard 15mm connector	Standard 15mm connector	Standard 15mm connector
Inner Cannula	Disposable • included in tray • also available separately	Disposable • included in tray • also available separately	Disposable • included in tray • also available separately	Reusable • included in tray
Materials (Outer Cannula, flange, cuff)	Non-DEHP PVC	Non-DEHP PVC	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})
MRI Compatibility	Cuffed: MR Conditional Cuffless: MR Safe	Cuffed: MR Conditional Cuffless: MR Safe		Cuffed: MR Conditional Cuffless: MR Safe
Accessories	Inner cannula, obturator, neck strap, TTH	Inner cannula, obturator, neck strap	Inner cannula, obturator, neck strap, TTH	Inner cannula, obturator, neck strap

Substantial Equivalence Discussion:

Indications for Use:
The indications for use of the subject devices are equivalent to the predicate device (K142296) and same as the reference devices (K150844), in that all three are intended to provide tracheal access for airway management.

Technological Characteristics:
The subject, predicate (K142296) and reference devices (K150844) have the same technological characteristics: radiopaque outer cannula with tapered tip, flexible flange with integrated 15mm connector, inner cannula, low-pressure TaperGuard™ cuff, non-DEHP PVC materials, MRI compatibility and patient population

The subject and reference devices (K051416) have the same technological characteristics: distal or proximal extension configurations, 90° curve of outer cannula and patient population

The subject, predicate and reference devices were tested to comply with FDA recognized standards for airway devices, ISO 5366 and ISO 5356-1.

To conclude, the subject device and legally marketed predicate device (K142296) share the same intended use, similar indications for use, and same technological characteristics including a radiopaque outer cannula, flexible flange with integrated 15mm connector, low-pressure TaperGuard™ cuff, non-DEHP PVC materials, disposable inner cannula and MRI compatibility. Additionally, reference devices (K051416, K150844) with same intended use and similar technological characteristics further strengthen the safety and performance related to the 90° curve of the outer cannula, size range (5.0mm to 8.0mm), the distal/proximal extension configuration as well as PDT indications.

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.

VII. 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 5366 and ISO 5356-1), as well as additional 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 recognized consensus standard testing in accordance with ISO 5366 and ISO 5356-1, including visual inspection, dimensional verification, cuff leak test, cuff inflation test, cuff herniation test, cuff resting diameter test, head cannula pull force test, inner cannula head pull force and protrusion test, obturator resistance test, kink resistance test and connector strength test.

In addition to above testing, bench testing in accordance with 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
- Skin Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Implantation
- Chemical Characterization
- Genotoxicity
- Subacute Toxicity/ Subchronic Toxicity
- Chronic Toxicity
- Carcinogenicity
- 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™ Adult Flexible Tracheostomy Tube XLT with Disposable Inner Cannula 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}.

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

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

VIII. CONCLUSION

Based on the information provided in this premarket notification submission, including intended use, device comparisons and performance testing, the Shiley™ Adult Flexible Tracheostomy Tube XLT with Disposable Inner Cannula 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™ Adult Flexible Tracheostomy Tube XLT with Disposable Inner Cannula are considered substantially equivalent to the predicate devices currently marketed for the same intended use.