October 6, 2025

Covidien LLC
Alicia Burkhardt
Senior Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K250173
Trade/Device Name: Shiley™ Oral RAE Tracheal Tube Cuffless, Murphy Eye (113-XX)
Shiley™ Nasal RAE Tracheal Tube Cuffless, Murphy Eye (114-XX)
Shiley™ Oral RAE Tracheal Tube Cuffed, Murphy Eye (115-XX)
Shiley™ Oral RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye (115-XXOR)
Shiley™ Nasal RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye (119-XXNR)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: September 8, 2025
Received: September 8, 2025

Dear Alicia Burkhardt:

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)*
K250173

Device Name
Shiley™ Oral RAE Tracheal Tube Cuffless, Murphy Eye (113-XX), Shiley™ Nasal RAE Tracheal Tube Cuffless, Murphy Eye (114-XX), Shiley™ Oral RAE Tracheal Tube Cuffed, Murphy Eye (115-XX), Shiley™ Oral RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye (115-XXOR), Shiley™ Nasal RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye (119-XXNR)

Indications for Use *(Describe)*
The devices are indicated for airway management in patients, during surgical procedures involving the head, neck, or mouth, to provide a clear surgical field by directing the circuit and connectors away from the operative area and reduce the risk of kink.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information for the Shiley™ Oral/Nasal RAE Tracheal Tube, Murphy Eye 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:	Alicia Burkhardt Senior Regulatory Affairs Specialist Phone: (704) 473-5389 Email: alicia.burkhardt@medtronic.com
Date:	January 21, 2025

II. DEVICE

Trade or Proprietary Name:	a) Shiley™ Oral RAE Tracheal Tube Cuffless, Murphy Eye b) Shiley™ Nasal RAE Tracheal Tube Cuffless Murphy Eye c) Shiley™ Oral RAE Tracheal Tube Cuffed Murphy Eye d) Shiley™ Oral RAE Tracheal Tube with TaperGuard™ Cuff Murphy Eye e) Shiley™ Nasal RAE Tracheal Tube with TaperGuard™ Cuff Murphy Eye
Common Name:	Tracheal Tube
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: Hangzhou Bever Medical Devices Co., Ltd.
Predicate Trade Name: BEVER™ Endotracheal Tube Preformed without Cuff Oral/Nasal

Predicate 510(k): K111401

Reference Device:

Predicate Manufacturer: Covidien LLC
Predicate Trade Name: Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP

Predicate 510(k): K233341

Reference Device:

Reference Manufacturer: Covidien LLC
Reference Trade Name: Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP

Reference 510(k): K223130

Table 1. Predicate & Reference Device Summary Table

	Family (Subject Devices)	Products	Predicate Device	Reference Devices
A	Shiley™ Oral RAE Tracheal Tube Cuffless, Murphy Eye	113-XX	BEVER™ Endotracheal Tube Preformed without Cuff Oral/Nasal (K111401)	Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP (K223130)
B	Shiley™ Nasal RAE Tracheal Tube Cuffless, Murphy Eye	114-XX		
C	Shiley™ Oral RAE Tracheal Tube Cuffed, Murphy Eye	115-XX		Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP (K233341)
D	Shiley™ Oral RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye	115-XXOR		Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP (K223130)
E	Shiley™ Nasal RAE Tracheal Tube with TaperGuard™ Cuff, Murphy Eye	119-XXNR		

IV. DEVICE DESCRIPTION

The subject device of this premarket 510(k) notification is referred to as Shiley™ Oral/Nasal RAE Tracheal Tube, Murphy Eye. The Shiley™ Oral/Nasal RAE Tracheal Tube, Murphy Eye has a translucent polyvinyl chloride (PVC) tube shaft with a radiopaque filament along its length. The subject device is offered as cuffless or cuffed in various sizes, for either oral or nasal use. All tubes are single use, sterilized by ethylene oxide, and supplied with a standard 15mm connector. The subject device and its packaging are not made with rubber latex or DEHP.

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, and number of murphy eyes.

a) Shiley™ Oral RAE Tracheal Tube Cuffless, Murphy Eye
b) Shiley™ Nasal RAE Tracheal Tube Cuffless Murphy Eye
c) Shiley™ Oral RAE Tracheal Tube Cuffed Murphy Eye
d) Shiley™ Oral RAE Tracheal Tube with TaperGuard™ Cuff Murphy Eye
e) Shiley™ Nasal RAE Tracheal Tube with TaperGuard™ Cuff Murphy Eye

V. INTENDED USE

The subject device is intended for oral or nasal intubation of the trachea.

VI. INDICATIONS FOR USE

The device is indicated for airway management in patients, during surgical procedures involving the head, neck, or mouth, to provide a clear surgical field by directing the circuit and connectors away from the operative area and reduce the risk of kink.

VII. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject devices are substantially equivalent to the predicate devices (K233341 & K111401). 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:***	***Reference Device:***
	Shiley™ Oral/Nasal RAE Tracheal Tube, Murphy Eye	BEVER™ Endotracheal Tube Preformed without Cuff Oral/Nasal (K111401)	Shiley™ Oral/Nasal Endotracheal Tube Intermediate Cuff, Non DEHP (K233341)	Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP (K223130)
Intended Use	Oral or nasal intubation of the trachea.	Oral or nasal intubation of the trachea for airway management.	Oral or nasal intubation of the trachea for airway management.	Oral or nasal intubation of the trachea for airway management.
Indications for Use	The device is indicated for airway management in patients, during surgical procedures involving the head, neck, or mouth, to provide a clear surgical field by directing the circuit and connectors away from the operative area and reduce the risk of kink.	The device is indicated for airway management by oral or nasal intubation of the trachea during mechanical ventilation and anesthesia.	The device is intended for oral/nasal intubation of the trachea for anesthesia and is indicated for airway management.	The device is intended for use in facilitating oral or nasal intubation of the trachea.
Patient Population	Pediatric and Adults	Pediatric and Adults	Pediatric and Adults	Pediatric
Use	Single patient use	Single patient use	Single patient use	Single patient use
Sterilization	Ethylene Oxide (SAL of 10^{-6})	Ethylene Oxide	Ethylene Oxide (SAL of 10^{-6})	Ethylene Oxide (SAL of 10^{-6})
Shelf Life	5 years	4 years	5 years	5 years
MRI Compatibility	MR Safe or MR Conditional	N/A	MR Conditional	MR Conditional

Materials	Non DEHP PVC	PVC	Non DEHP PVC	Non DEHP PVC
Device Design	ISO 5361, ISO 5356-1	ISO 5361	ISO 5361, ISO 5356-1	ISO 5361, ISO 5356-1
Standard 15mm Connector	Yes	Yes	Yes	Yes
Tube Curvature	RAE	RAE	Magill	Magill
Product Size Range	3.0 – 9.0mm	3.0 – 9.0mm	3.0 - 10.0 mm	2.5 – 6.0 mm
Cuff Design	Cuffless, or High-Volume, Low Pressure (HVLP) Cylindrical Shaped Cuff, or Low-Pressure Taper Shaped Cuff	Cuffless	High-Volume, Low Pressure (HVLP) Cylindrical Shaped Cuff	Low-Pressure, Taper Shaped Cuff

Substantial Equivalence Discussion:

Indications for Use:

The subject and predicate devices (K111401) have similar indications for use. The predicate device is indicated for airway management by oral or nasal intubation of the trachea during mechanical ventilation and anesthesia The subject devices are indicated for airway management in patients, during surgical procedures involving the head, neck, or mouth, to provide a clear surgical field by directing the circuit and connectors away from the operative area and reduce the risk of kink. However, both predicate and subject devices are RAE tracheal tubes. Therefore, the additional phrase "in patients, during surgical procedures involving the head, neck, or mouth, to provide a clear surgical field by directing the circuit and connectors away from the operative area and reduce the risk of kink" in the subject devices' indications for use does not raise new questions of safety or effectiveness as the clarifying language meets the definition of a RAE tracheal tube.

Technological Characteristics:
The subject and predicate (K111401) devices have the same technological characteristics: RAE curve, 15 mm connector, similar size range, presence of murphy eye, and cuffless design (113-XX, 114-XX).

The subject and reference (K233341) devices have the same technological characteristics: 15 mm connector, inflation system (for cuffed devices 115-XX, 115-XXOR, 119-XXNR), non-DEHP PVC materials, and high-volume low-pressure cylindrical shaped cuff (115-XX).

The subject and reference (K223130) devices have the same technological characteristics: 15 mm connector, inflation system (for cuffed devices 115-XX, 115-XXOR, 119-XXNR), non-DEHP PVC materials, and low-pressure taper shaped cuff (115-XXOR, 119-XXNR).

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 (K111401) share the same intended use, indications for use, RAE tube design and other design features like murphy eye, lack of cuff. Additionally, reference devices (K233341 and K223130) 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 devices' cuff shape.

While the subject device differs from the predicate devices 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 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™ Oral/Nasal RAE Tracheal Tube, Murphy Eye 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™ Oral/Nasal RAE Tracheal Tube, Murphy Eye 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™ Oral/Nasal RAE Tracheal Tube, Murphy Eye are considered substantially equivalent to the predicate and reference devices currently marketed for the same intended use.