DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 11, 2015

Covidien
Danielle Mueller
Regulatory Affairs Manager
6135 Gunbarrel Ave
Boulder, CO 80301

Re: K151381
Trade/Device Name: Mallinckrodt™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: November 9, 2015
Received: November 10, 2015

Dear Danielle Mueller:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151381

Device Name
Mallinckrodt Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye

Indications for Use *(Describe)*
The oral/nasal cuffless non-DEHP pediatric endotracheal tube with Murphy eye is indicated for oral or nasal intubation of the trachea for airway management.

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

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510(k) Summary for the use of the Mallinckrodt™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye.

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	December 10, 2015
Contact Person:	Danielle Mueller Regulatory Affairs Manager (303) 305-2603
Proprietary Name:	**Mallinckrodt™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye**
Common Name:	Tracheal Tube
Device Classification Regulation:	21 CFR 868.5730 – Class II
Device Product Code & Panel:	BTR
Predicate Devices:	**BEVER™ Endotracheal Tube (K111401)**

Device Description
The subject device is an oral/nasal cuffless pediatric endotracheal tube with Murphy eye. The tube incorporates a Magill curve, radiopaque line, and ISO 15mm connector. It is manufactured from materials without latex or DEHP.

Indications for Use/Intended Use
The oral/nasal cuffless non-DEHP pediatric endotracheal tube with Murphy eye is indicated for oral or nasal intubation of the trachea for airway management.

Technological Characteristics Comparison
The subject device is substantially equivalent to the predicate in terms of technological characteristics. Both devices are designed in accordance with ISO 5361 and have the following features in common: cuffless, standard 15mm connector, Magill curve, Murphy eye, similar size range, and similar material composition.

	SUBJECT	PREDICATE
	Mallinckrodt™ Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye	**BEVER™ Oral/Nasal Endotracheal Tube Cuffless [K111401]**
Intended Use	Oral or nasal intubation of the trachea for airway management.	Oral or nasal intubation of the trachea for airway management during mechanical ventilation and anesthesia.
Patient Population	Pediatrics	Pediatrics, Adults
Use	Single patient	Single patient
DEVICE DESIGN		
Tube Design	Per ISO 5361:2012	Per ISO 5361:1999
Magill Curve	Yes	Yes
Murphy Eye	Yes	Yes
Radiopaque Line	Yes	Yes
Size Range	2.0 – 7.0mm	2.0 – 9.0mm
Sterilization	EtO	EtO
Shelf Life	5 years	4 years
Tube Material	Medical grade PVC with a non-DEHP plasticizer	Medical grade PVC

Substantial Equivalence – Non-Clinical Evidence
The subject device met all acceptance criteria for verification testing per ISO 5361:2012; therefore, it can be considered substantially equivalent to the predicate in terms of performance. Additionally, biocompatibility testing was performed per ISO 10993-1:2009 including the following: cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, subchronic toxicity, implantation, chemical characterization, and toxicological risk assessment. The device met all biocompatibility requirements for its intended use. Solvent extraction testing was performed to confirm the content of DEHP is less than 0.1% w/w in the device.

Substantial Equivalence – Clinical Evidence
N/A – Clinical evidence was not necessary to show substantial equivalence.

Substantial Equivalence – Conclusions
No new questions of safety and effectiveness have been raised. From the evidence presented in the premarket notification, the subject devices can be considered substantially equivalent.