May 7, 2018

Cook Incorporated
Paul Meyer
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47404

Re: K180034
Trade/Device Name: Weinmann Tracheostomy Exchange Set
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: April 9, 2018
Received: April 10, 2018

Dear Paul Meyer:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180034

Device Name
Weinmann Tracheostomy Exchange Set

Indications for Use *(Describe)*
The Weinmann Tracheostomy Exchange Set is intended for adult tracheostomy tube exchange

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

Weinmann Tracheostomy Exchange Set
21 CFR §807.92
Date Prepared: April 30, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Paul Meyer Hui Ouyang, PhD, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 339-2235 x105299
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Device Information:

Trade Name:	Weinmann Tracheostomy Exchange Set
Device Common Names:	Tracheostomy tube exchange set
Classification Regulation:	21 CFR 868.5800, JOH
Device Classification:	Class II
Review Panel:	Anesthesiology
Office of Device Evaluation:	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices (DAGRID) Anesthesiology Devices Branch (ANDB)

Predicate Device:

The Weinmann Tracheostomy Exchange Set is substantially equivalent to the predicate device, the Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Sets (Cook Incorporated, K133597), cleared for market by FDA on April 18, 2014.

Device Description:

The subject device, the Weinmann Tracheostomy Exchange Set, includes a Ciaglia Blue Rhino Percutaneous Tracheostomy Dilator (cleared under K133597), five Ciaglia loading dilators (21-, 24-, 26-, 27-, and 28-Fr; cleared under K133597), an 8-Fr Cook Airway Exchange Catheter (cleared under K162729), and two Rapi-Fit Adapters (cleared under K162729).

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The Ciaglia Blue Rhino Percutaneous Tracheostomy Dilator is designed to be advanced over an airway exchange catheter into an existing tracheostomy tube to dilate the stoma, to be prepared for replacement of a new tracheostomy tube. The dilator is 38.0-Fr in outer diameter and 20 centimeters long. This dilator has a depth marking to indicate the skin level, which is placed 11 centimeters from the distal tip. Another feature of the device is the presence of hydrophilic coating on the distal 11 centimeters of the device.

The Ciaglia loading dilators are designed to be inserted into a new tracheostomy tube to facilitate dilation of the stoma and placement of the tube in the airway. The dilators are available in outer diameter of 21 to 28 Fr; all dilators are 20 centimeters long and curved at the distal end.

The airway exchange catheter is designed to be inserted into the previously existing tracheostomy tube in patients prior to removal. The airway exchange catheter keeps the airway open during dilation and placement of a new tracheostomy tube. The airway exchange catheter is 8.0 Fr in outer diameter and 45 centimeters long. The distal end of the airway exchange is a blunt tip with rounded edges.

Two Rapi-Fit adapters (one with a 15-mm connector, and one with a Luer lock connector) are provided to be used with the airway exchange catheter for oxygenation when the requirement for oxygen is high in patients but the tracheostomy tube is not in place. The 15 mm Rapi-Fit adapter is designed for attachment to traditional ventilator sources that are low pressure sources, or so-called continuous positive airway pressure (CPAP) ventilators. The Luer Lock Rapi-Fit adapter is designed for attachment to a high-pressure jet ventilation oxygen source. The Luer Lock connection is a male Luer Lock that is compatible with the standard Luer fitting of an oxygen tube which is connected to an oxygen source.

Indication for Use:

The Weinmann Tracheostomy Set is intended for adult tracheostomy tube exchange.

Comparison to Predicate:

The subject device is substantially equivalent to the predicate device in that they have the same intended use, which is to assist placement of a tracheostomy tube. Furthermore, they have similar indications for use, technological characteristics, method of operation,

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and materials of construction. The substantial equivalence comparison with the predicate device is provided in Table 1.

Table 1: Substantial Equivalence Comparison Table

		Predicate Device	**Subject Device**
		Ciaglia Percutaneous Tracheostomy Introducer Set, Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Set/Tray K133597	**Weimann Tracheostomy Exchange Set**
Regulation		21 CFR § 868.5800, Tracheostomy tube and tube cuff	IDENTICAL TO PREDICATE
Product Code		JOH, tracheostomy tube and tube cuff	IDENTICAL TO PREDICATE
Classification		II	IDENTICAL TO PREDICATE
Indication for Use		For percutaneous dilational tracheostomy for management of the airway in adults only	The Weinmann Tracheostomy Exchange Set is intended for adult tracheostomy tube exchange
One-time Use		Yes	IDENTICAL TO PREDICATE
Recommended Insertion Site		Between the 1st and 2nd tracheal cartilages or between the 2nd and 3rd tracheal cartilages	IDENTICAL TO PREDICATE
Placement		Percutaneous technique	IDENTICAL TO PREDICATE
Duration of Use		Limited (≤ 24 hours)	IDENTICAL TO PREDICATE
Ciaglia Blue Rhino Tracheostomy Dilator	**Length**	20 cm	IDENTICAL TO PREDICATE
	Outer Diameter	38 Fr (max)	IDENTICAL TO PREDICATE
	Material	Polyurethane	IDENTICAL TO PREDICATE
	Depth Marking	Yes	IDENTICAL TO PREDICATE
	Hydrophilic Coating	Yes	IDENTICAL TO PREDICATE
Loading Dilators	**Sizes**	18, 21, 24, 26, 27, 28, 32, 36, and 38 Fr	21, 24, 26, 27, and 28 Fr
	Tip	Tapered and curved	IDENTICAL TO PREDICATE
	Material	Vinyl and Polyurethane	Polyurethane
	Ink Marking	Yes	IDENTICAL TO PREDICATE
Additional Components		Introducer needles Introducer dilator Wire guide Guiding catheter	Exchange catheter Two Rapi-Fit adapters
Sterilization Method		Ethylene Oxide	IDENTICAL TO PREDICATE
Packaging		Thermoform tray with a Tyvek® lid	Tyvek® Pouch

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The differences in Indication for Use and technological characteristics between the predicate and subject devices do not raise different questions of safety or effectiveness because:

- Indication for Use: the predicate is used for the initial placement of a tracheostomy tube when no tracheostomy exists. The subject device is used to exchange an existing tracheostomy tube to a new one. Initial placement of the tracheostomy tube as in the predicate device indication requires creating a percutaneous opening into the patient's airway through the tracheal cartilages. This access procedure is not required for the subject device as there is already a tracheostomy tube in place. The exchange aspect of the subject device does not raise different questions of safety or effectiveness as comparing to the predicate.
- Additional components: the exchange catheter and adapters included in the subject device set have been previously cleared under K162729.

Technological Characteristics:

The subject device, Weinmann Tracheostomy Exchange Set, was subjected to applicable non-clinical testing to ensure reliable design and performance under the specified design requirements. Testing includes:

- Dimensional and Compatibility Evaluation of the subject device (Accelerated/Real Time Aged).
- Biocompatibility testing – Data from the Ciaglia Blue Rhino Percutaneous Tracheostomy Introducer Set/Tray cleared under K133597 and the Cook Airway Exchange Catheter cleared under K162729 were leveraged to mitigate biocompatibility testing. Test results indicate that all materials are biocompatible.

The results of these tests show that the subject device meets the design input requirements based on the intended use and support the conclusion that the subject device does not raise different questions of safety or effectiveness and is substantially equivalent to the predicate device.