COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
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Ciaglia Percutaneous Tracheostomy Introducer Set
Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Set/Tray
Ciaglia Blue Rhino® G2 Advanced Percutaneous Tracheostomy Introducer Set/Tray

APR 18 2014

21 CFR §807.92

Date Prepared: April 15, 2014

Submitted By:

Applicant:	Cook Incorporated
Contact:	Sean Spence, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x105127
Contact Fax Number:	(812) 332-0281

Device Information:

Trade names:	Ciaglia Percutaneous Tracheostomy Introducer Set Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Set/Tray Ciaglia Blue Rhino® G2 Advanced Percutaneous Tracheostomy Introducer Set/Tray
Common name:	Tracheostomy Introducers
Classification Name:	Tracheostomy tube and tube cuff
Regulation:	21 CFR §868.5800
Product Code:	JOH

Predicate Device:

K041348: Portex® Ultraperc® Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer

Device Description:

The Cook Ciaglia percutaneous tracheostomy devices are designed for percutaneous dilational tracheostomy for management of the airway. More specifically, the devices allow for two approaches to the dilation of the stoma: serial dilation (Ciaglia Percutaneous Tracheostomy Introducer Set) or single-stage dilation (Blue Rhino® and Blue Rhino® G2 Advanced Percutaneous Tracheostomy Introducer Set). Serial dilation is achieved using numerous progressively larger dilators. Single-stage dilation is achieved with a single rhino-horn-shaped dilator using an in-and-out motion.

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The Cook Ciaglia percutaneous tracheostomy devices are sold sterile for single use. There are multiple configurations that include various set and tray components (Table 1) associated with the procedure and/or in gaining percutaneous access.

Table 1: Set/Tray Components

Components		
Loading dilators	Gauze sponges	Endotracheal tube accessory
Guiding catheter	Introducer needles	Suture & needle
Access dilators	Catheter needles	Tracheostomy tube holder
Wire guide	Needle holder cup	Drape
Scalpels	Clamp	Split dressing
Syringes	Infiltration needles	Antiseptic skin prep
Lubricated jelly	Filter straw	Local anesthetic
Ointment		

Indications for Use:

a. The **Ciaglia Percutaneous Tracheostomy Introducer Set** is intended for percutaneous dilational tracheostomy for management of the airway in adults only.
Tube placement, using the technique described herein, should be performed in a controlled setting (e.g., ICU or operating room) with the assistance of trained personnel.

b. The **Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Set/Tray** is intended for percutaneous dilational tracheostomy for management of the airway in adults only.
Tube placement, using the technique described herein, should be performed in a controlled setting (e.g., ICU or operating room) with the assistance of trained personnel.

c. The **Ciaglia Blue Rhino® G2 Advanced Percutaneous Tracheostomy Introducer Set/Tray** is intended for percutaneous dilational tracheostomy for management of the airway in adults only.
Tube placement, using the technique described herein, should be performed in a controlled setting (e.g., ICU or operating room) with the assistance of trained personnel.

Substantial Equivalence:

The Cook Ciaglia percutaneous tracheostomy devices are substantially equivalent in indications for use to the predicate. Both state their purpose as percutaneous dilational tracheostomy for management of the airway. The predicate specifically lists components used (e.g., wire guide, dilator) but those are implied whenever referencing percutaneous access. These differences do not raise new concerns and support a conclusion of substantial equivalence.

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Table 2: Substantial Equivalence Comparison – Ciaglia and Serial Dilator Predicate

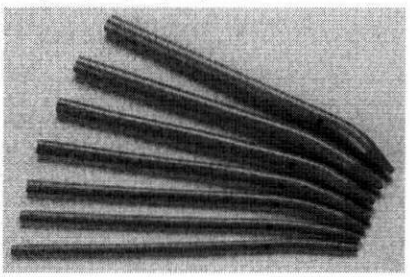
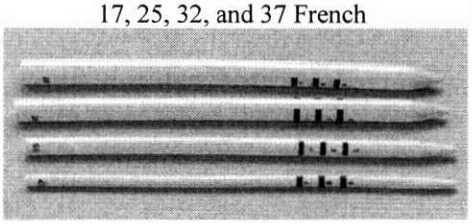
	SUBJECT DEVICES	PREDICATE
	Ciaglia Percutaneous Tracheostomy Introducer Set	Portex® Ultraperc® Percutaneous Dilation Tracheostomy Kit with **Serial Dilators** or Single Stage Dilator, Blue Line Ultra Trach. Tube and Introducer
510(k)	Subject of this submission	K041348
Regulation	21 CFR §868.5800, Tracheostomy tube and tube cuff	Same
Product Code	JOH, tracheostomy tube and tube cuff	BTO, tube, tracheostomy (w/wo connector)
Classification	II	Same
Indications for Use	.... is intended for percutaneous dilational tracheostomy for management of the airway in adults only ...should be performed in a controlled setting...	Indicated to create a percutaneous dilational tracheostomy using guidewire dilators and components of these kits that allow for tracheal access for airway management for use in adults only
Recommended Insertion Site	Between the first and second tracheal cartilages or between the second and third tracheal cartilages	Same
Duration of Use	Limited duration (≤ 24 hours)	Same
Placement	Percutaneous technique	Same
Patient Population	Adult patients requiring prolonged ventilatory support	Same
Sterilization	EtO	EtO
Shelf-Life	3 years	UNKNOWN
Packaging	Thermoform tray with a Tyvek® lid	Polymer bag with Tyvek opening
Tracheostomy Tube	Not sold with tracheostomy tube	Sold with tracheostomy tube in primary packaging
Serial Dilator Overview	18, 21, 24, 28, 32, 36, and 38 French 	17, 25, 32, and 37 French 
Material	Vinyl	UNKNOWN
Black Ink Markings	Single skin level mark	Multiple specific depth marks
Tip Configuration	Tapered and curved	Tapered and straight
Tracheostomy Tube Loading	Serial dilators serve as tracheostomy tube loading dilators for final placement	Separate tracheostomy tube loading dilator included

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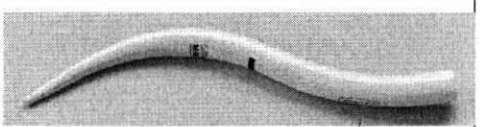
Table 3: Substantial Equivalence Comparison – Ciaglia Blue Rhino / Blue Rhino G2 and Portex Single-Stage Predicate

	SUBJECT DEVICES	PREDICATE
	Ciaglia Blue Rhino, and Ciaglia Blue Rhino G2 Advanced Percutaneous Tracheostomy Introducer Sets	Portex® Ultraperc® Percutaneous Dilation Tracheostomy Kit with Serial Dilators or **Single Stage Dilator**, Blue Line Ultra Trach. Tube and Introducer
510(k)	Subject of this submission	K041348
Regulation	21 CFR §868.5800, Tracheostomy tube and tube cuff	Same
Product Code	JOH, tracheostomy tube and tube cuff	BTO, tube, tracheostomy (w/wo connector)
Classification	II	Same
Indications for Use	.... is intended for percutaneous dilational tracheostomy for management of the airway ...should be performed in a controlled setting...	Indicated to create a percutaneous dilational tracheostomy using guidewire dilators and components of these kits that allow for tracheal access for airway management for use in adults only
Contraindicated for Pediatrics	Yes	Same
Recommended Insertion Site	Between the first and second tracheal cartilages or between the second and third tracheal cartilages	Same
Duration of Use	Limited duration (≤ 24 hours)	Same
Placement	Percutaneous technique	Same
Patient Population	Adult patients requiring prolonged ventilatory support	Same
Sterilization	EtO	EtO
Shelf-Life	3 years	UNKNOWN
Packaging	Thermoform tray with a Tyvek® lid	Plastic bag with Tyvek® opening
Tracheostomy Tube	Set or Tray sold individually and co-packaged with a tracheostomy tube	Tracheostomy tube present in primary packaging
Single-Staged Dilator Overview	Curved Single-Staged Dilator  Blue Rhino  Blue Rhino G2	 Sigmoid Curved Single-Staged Dilator
Material	Blue radiopaque polyurethane	UNKNOWN
Surface Characteristics	Blue Rhino = Smooth Blue Rhino G2 = Crosshatch Handle and Longitudinally Grooved Distal Portion	Texture Handle Portion and Smooth Distal Portion
Tip Configuration	Tapered and curved	Same
Black Ink Markings	Single skin level mark	Same
Hydrophilic Coating	PVP based Hydrophilic Coating	UNKNOWN base Hydrophilic Coating

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As shown in Table 2, differences in the subject serial dilators and the predicate serial dilators are packaging, presence or absence of a tracheostomy tube, range of serial dilators, material, tracheostomy tube loading, curvature at the distal tip, and depth markings. Table 3 shows differences in the subject single-stage dilators and the predicate are packaging, presence or absence of a tracheostomy tube, shape, material and texture. The differences in characteristics do not raise new concerns and support a conclusion of substantial equivalence. This conclusion was derived by comparing the product literature, specifications, and by performance testing.

Summary of Non-Clinical Testing:
The following tests were performed to demonstrate that the Cook Ciaglia tracheostomy devices met applicable design and performance requirements and support a determination of substantial equivalence.

- Tracheostomy Tube Fit / Removal – Testing showed that the appropriate loading dilator can successfully be inserted into the intended tracheostomy tube and will not fall out under its own weight, and can be successfully removed
- Tensile – Testing showed that the peak tensile load of each test article was greater than or equal to the acceptance criterion
- Compression – Testing showed that the test article will withstand the axial peak compressive load without kinking
- Flexibility with Guiding Catheter – Testing showed the mean force to displace the tip of the guiding catheter was less than the mean to displace the dilator
- Fracture – Testing showed the test article met the predetermined acceptance criteria
- Durability – Testing showed the test article met the predetermined acceptance criteria
- 3 Point Bend – Testing showed the load to deflect the dilators was less than or equal to the load of the predicate
- Insertion Force – Testing showed the average insertion load of the test article was less than or equal to the predicate
- Performance following aging – Testing showed the subject devices continue to meet applicable design input requirements following aging
- Biocompatibility – The proposed devices were classified as external communicating devices with Tissue/Bone/Dentin contact for $\leq$ 24 hours. The following tests were completed and the biocompatibility was deemed acceptable: Cytotoxicity, Sensitization, Intracutaneous Reactivity, and Pyrogenicity.

In addition, human factors hazard analysis and simulated use testing (usability study) were conducted.

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Summary of Clinical Performance:

Clinical tests were not required to demonstrate substantial equivalence of the Cook Ciaglia percutaneous tracheostomy devices as compared to the predicate devices. However, since the subject devices have a well-established history of clinical use, an evaluation of published clinical evidence was used to substantiate a history of safe and effective use. A total of 24 articles, incorporating 8,726 patients treated with Cook devices, were summarized. Limited clinical evidence on the predicate Portex Ultraperc® Percutaneous Dilation Tracheostomy kit was also found in 4 articles, incorporating 1,036 patients. Overall, the clinical evidence demonstrates that the subject devices are as safe and effective as the predicate device when used in percutaneous dilational tracheostomy for management of the airway.

Conclusion:

Based on the comparison information, non-clinical performance testing, and published clinical evidence, the Cook Ciaglia percutaneous tracheostomy are substantially equivalent to the predicate Portex® Ultraperc® Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer (K041348).

Portex® and Ultraperc® are registered trademarks of Smiths Medical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 18, 2014

Cook Incorporated
Mr. Sean Spence, RAC
Regulatory Affairs Team Lead
Official Correspondent
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K133597
Trade/Device Name: Ciaglia Percutaneous Tracheostomy Introducer Set
Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Set/Tray
Ciaglia Blue Rhino® G2 Advanced Percutaneous Tracheostomy Introducer Set/Tray
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube
Regulatory Class: Class II
Product Code: JOH
Dated: March 17th, 2014
Received: March 18th, 2014

Dear Mr. Spence:

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.

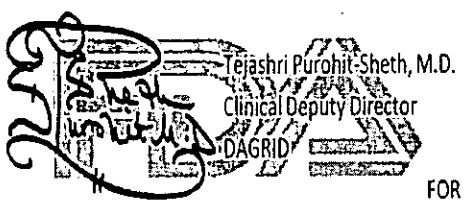
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



FOR

Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133597

Device Name
Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Set/Tray

Indications for Use *(Describe)*
The Ciaglia Blue Rhino Percutaneous Tracheostomy Introducer Set/Tray is intended for percutaneous dilational tracheostomy for management of the airway in adults only.

Tube placement, using the technique described herein, should be performed in a controlled setting (e.g., ICU or operating room) with the assistance of trained personnel.

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)

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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)*
K133597

Device Name
Ciaglia Percutaneous Tracheostomy Introducer Set

Indications for Use *(Describe)*
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Tube placement, using the technique described herein, should be performed in a controlled setting (e.g., ICU or operating room) with the assistance of trained personnel.

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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)*
K133597

Device Name
Ciaglia Blue Rhino® G2 Advanced Percutaneous Tracheostomy Introducer Set/Tray

Indications for Use *(Describe)*
The Ciaglia Blue Rhino G2 Advanced Percutaneous Tracheostomy Introducer Set/Tray is intended for percutaneous dilational tracheostomy for management of the airway in adults only.

Tube placement, using the technique described herein, should be performed in a controlled setting (e.g., ICU or operating room) with the assistance of trained personnel.

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