JUL 2 9 2004

COOK®

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510(k) SUMMARY

Submitted By: COOK INCORPORATED
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402-0489

Contact: Jennifer Bosley, MBA, RAC
Regulatory Affairs Coordinator
Tel: (812) 339-2235 Fax: (812) 332-0281

Date Prepared: July 27, 2004

510(k) #: K041044

Device:
Trade Name: Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer
Common/Usual Name: Tracheostomy Tube Introducer
Classification Name: Tracheostomy Tube and Tube Cuff, 21 CFR § 868.5800
Class: Class II
Product/Panel Code: JOH—Anesthesiology Device Panel

Intended Use:
The Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer is intended for controlled elective subcricoid insertion of a tracheostomy tube.

Substantial Equivalence:
The subject device is similar with respect to intended use and/or design features to the predicate devices in terms of section 510(k) substantial equivalence. The subject device is safe and effective and is substantially equivalent to the predicate devices.

Manufacturer	Device	510(k) #
Cook Incorporated	Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer	Class I Exempt
Portex Ltd.	Portex Percutaneous Dilatational Tracheostomy Kit	K022212

Device Description:
The Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer consists of an inflatable balloon on a double lumen 5 Fr inner coaxial catheter shaft; the loading section of the coaxial catheter shaft will be available in 21, 24, 26, 27 and 28 French sizes. The length of the catheter shaft is 21.5 cm with a Luer port for inflation and a Luer port for the wire guide. The balloon is 5.4 cm x 1.6 cm, with a rated burst pressure of 6 atm. The set components include the balloon catheter, catheter access needle, 0.035" wire guide, dilator, 20 cc controlled syringe and other vendor components for percutaneous insertion. The set is supplied sterile and intended for one-time use.

Test Data:
Testing includes biocompatibility testing, tensile strength, fatigue, air and liquid leakage; burst pressure and inflation/deflation time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2004

Ms. Jennifer Bosley
Regulatory Affairs Coordinator
Cook, Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47402-0489

Re: K041044
Trade/Device Name: Ciaglia Cheetah Percutaneous Tracheostomy Introducer Set
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: June 28, 2004
Received: June 29, 2004

Dear Ms. Bosley:

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.

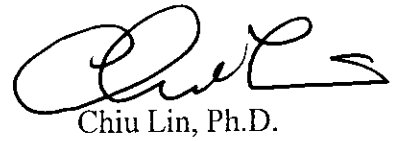
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K041044

Device Name: Ciaglia Cheetah™ Percutaneous Tracheostomy Introducer Set

Indications for Use:

The Ciaglia Cheetah™ Percutaneous Tracheostomy Introducer Set is intended for controlled elective subcricoid insertion of a tracheostomy tube.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041044