K072148

510(k) SUMMARY

OCT 3 2007

Submitted By: Susanne Galin
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2296
02 August 2007

Device:

Trade Name:	Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer
Proposed Classification Name:	Tracheostomy tube and tube cuff 21 CFR §868.5800, Product Code JOH
Indications for Use:	Used for controlled elective subcricoid insertion of a tracheostomy tube.

Predicate Devices:

The Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer is identical in terms of intended use and technological characteristics to the predicate Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer (K041044), and similar in terms of materials of construction.

Device Description:

The Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer is a device used to facilitate percutaneous entry into the trachea for placement of a tracheostomy tube. A separate, sterile tracheostomy tube is also included in an optional set.

The set consists of a balloon-tipped catheter loading dilator assembly, wire guide, introducer needle, needle holder cup, 14 French dilator, gauze pads, disposable syringe, measuring tape, disposable scalpel, lubricating jelly, and a large full-body drape with clear plastic window.

Substantial Equivalence:

The identical indications for use, technological characteristics, and similar materials of construction of the Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer as compared to the predicate device supports a determination of substantial equivalence.

Test Data:

Testing data are presented to demonstrate that the Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer meets applicable design and performance requirements.

- Balloon compliance and burst testing
- Failure load testing
- Withdraw force testing
- Tensile testing

The results of these tests provide reasonable assurance that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susanne Galin
Regulatory Affairs Specialist
Cook, Incorporated
750 Daniels Way
Post Office Box 489
Bloomington, Indiana 47402

OCT 3 ˇ 2007

Re: K072148
Trade/Device Name: Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: August 31, 2007
Received: September 4, 2007

Dear Ms. Galin:

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.

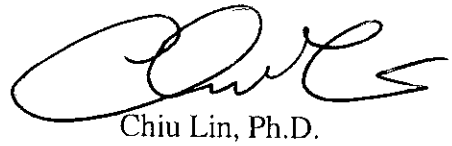
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K072148

Device Name: Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer

Indications for Use: Used for controlled elective subcricoid insertion of a tracheostomy tube.

Prescription Use XX OR Over-the-Counter Use____
(Per 21 CFR 801.109)

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
CDRH, Office of Device Evaluation (ODE)

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