K093469

510(k) SUMMARY

JAN - 8 2010

Submitted By: Susanne Galin, RAC
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2296
November 5, 2009

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:	Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer, 510(k) number K072148

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.

Substantial Equivalence:

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

Test Data:

Withdrawal Force Testing and Tensile Testing was presented to demonstrate that the Ciaglia Blue Dolphin™ Balloon Percutaneous Tracheostomy Introducer meets applicable design and performance requirements. 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 8 2010

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

Re: K093469
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: December 10, 2009
Received: December 11, 2009

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K093469

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K093469