AUG 1 4 2002

K021920

Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
750 Daniels Way
P.O. Box 489
Bloomington, In 47402
(812) 339-2235

Device: Trade Name: 7.0 Fr. Endobronchial Blocker
Proposed Classification Name: Tracheal/Bronchial Differential Ventilation Tube

Predicate Devices or Legally Marketed Devices:

Cook Bronchial Blocker	Marketed & Distributed by COOK INCORPORATED
Arndt Pediatric Endobronchial Blocker	Marketed & Distributed by COOK INCORPORATED
Univent Tube	Marketed & Distributed by Vitaid, LTD

Device Description

The catheter contains a balloon at its distal tip. The proximal end of the catheter is made up of a Y-fitting. One port of the Y-fitting is connected to a pilot balloon assembly. This balloon assembly facilitates inflation of the distal balloon and maintains inflation until it is released. The other port of the Y-fitting connects to the through lumen of the catheter which incorporates a removable looped guide wire that is used to help traverse the catheter along the length of a previously positioned bronchoscope. When the balloon catheter has been advanced to either the right or left bronchus, the guide loop is removed and discarded leaving the through lumen open.

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Indications for Use

The 7.0 Fr. Endobronchial Blocker is intended for use to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures which require one-lung ventilation.

Substantial Equivalence

The 7.0 Fr. Endobronchial Blocker is similar to the Cook Bronchial Blocker (D.C. #K962167), The Arndt Pediatric Endobronchial Blocker (D.C. #K002288) and the Univent Tube D.C. #K894337). The 7.0 Fr. Endobronchial Blocker is a modification of the Arndt Pediatric Endobronchial Blocker and the Cook Bronchial Blocker manufactured and marketed by Cook. The Univent Tube was cleared under Premarket Notification #K894337. The similar indications for use and technological characteristics of the 7.0 Fr. Endobronchial Blocker as compared to the predicate devices support a determination of substantial equivalency.

Test Data

The 7.0 Fr. Endobronchial Blocker was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Performance Testing
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as an Endobronchial Blocker.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

Ms. April Lavender
Vice President, Regulatory Affairs
Cook, Incorporated
P.O. Box 489
Bloomington, Indiana 47402

Re: K021920
Trade/Device Name: 7.0 Fr Endobronchial Blocker
Regulation Number: 21 CFR 868.5740; and 21 CFR 868.5720
Regulation Name: Tracheal/bronchial differential ventilation tube; and Bronchial tube
Regulatory Class: II
Product Code: CBI and BTS
Dated: July 12, 2002
Received: July 15, 2002

Dear Ms. Lavender:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology,
General Hospital, Infection Control
and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure

510(k) Number (if known): K021920

Device Name: 7.0 Fr. Endobronchial Blocker

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

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

510(k) Number_____