K013916

DEC 2 0 2001

9 510K SUMMARY

Submitted By:
Heidi Masten, RT(T), MBA
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235

Device:

Trade Name:	Melker Emergency Cricothyrotomy Catheter Set
Common/Usual Name:	Catheter, emergency airway access needle
Proposed Classification Name:	Emergency Airway Needle 21 CFR Part 868.5090 Class II

Intended Use:
The Melker Emergency Cricothyrotomy Catheter Set is used for emergency airway access.

- In patients whom conventional endotracheal intubation and ventilation cannot be performed.

The device will be supplied sterile and is intended for one-time use.

Device Description:

The Melker Emergency Cricothyrotomy Catheter with a standard inner diameter of 3.5, 4, or 6 mm and a length of either 3.8, 4.2, 7.5 cm with a proximal fitting and a coaxial dilator tapered to a 0.038-inch wire guide.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to currently marketed devices. This device is the same with respect to indications for use, material and physical characteristics to the Melker Cuffed Cricothyrotomy Catheter Set cleared under K010016 on 10/09/01.

Performance Information:

Specific performance of the device subject of this submission is assured through adherence to the firm's quality system procedures for device quality. Various device design specifications and quality specifications are used to produce a device that meets predetermined acceptance criteria. This is the same as for the Melker Cuffed Cricothyrotomy Catheter Set cleared under K010016 on 10/09/01.

Packaging Information:

Each unit is packaged and sealed within a Tyvek-Poly pouch and properly labeled.

Sterilization Information:

The Melker Emergency Cricothyrotomy Catheter Set will be sterilized using an Ethylene Oxide (ETO) gas cycle validated to assure a 10^{-6} sterility assurance level.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Ms. Heidi Masten
Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489

Re: K013916
Melker Emergency Cricothyrotomy Catheter Set
Regulation Number: 868.5090 and 868.5800
Regulation Name: Emergency Airway Needle and Tracheostomy Tube and Tube Cuff
Regulatory Class: Class II (two)
Product Code: 73 BWC, JOH
Dated: November 26, 2001
Received: November 27, 2001

Dear Ms. Masten:

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.

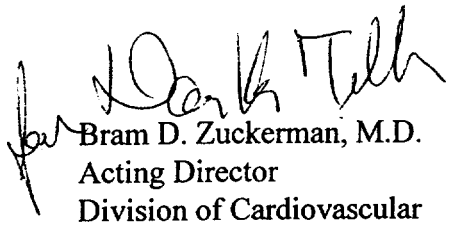
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name Melker Emergency Cricothyrotomy Catheter Set

Indications for Use:

Used for emergency airway access when conventional endotracheal intubation and ventilation cannot be performed.

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013916

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