

OCT 16 1998

K974774

**510(k) Premarket Notification
NV Guiding Catheter
COOK INCORPORATED**

Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235

Device:

Trade Name: Envy™ Guiding Catheter
Proposed Classification Name: 21 CFR Part 876.1200 (74DQO)

Predicate Devices:

The Envy™ Guiding Catheter has the same intended use, materials of construction, and technological characteristics as the COOK Coronary Guiding Catheter.

Device Description:

The Envy™ Guiding Catheter is used as a support catheter for interventional intracoronary devices. The device will be constructed of nylon and TFE with stainless steel braiding. The Envy™ Guiding Catheter outside diameter is 6.0 French and will be available in various lengths and various distal curves. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

The Envy™ Guiding Catheter is constructed using similar materials as the COOK Guiding Catheter. The device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by COOK INCORPORATED. This device will undergo sterilization similar to the devices currently marketed and distributed.



OCT 16 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. April Lavender, RAC
Vice President Regulatory Affairs
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Re: K974774
Trade Name: ENVY™ Guiding Catheter
Regulatory Class: II
Product Code: DQO
Dated: July 17, 1998
Received: July 20, 1998

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

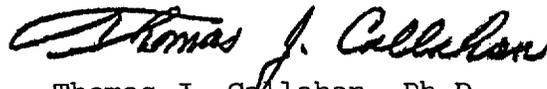
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Premarket Notification
NV Guiding Catheter
COOK INCORPORATED

510(k) Number (if known): K974774

Device Name: Envy™ Guiding Catheter

Indications for Use:

Used for the delivery of PTCA balloons and other various types of interventional cardiology devices. They are intended for use by physicians trained and experienced in PTCA and interventional cardiology techniques. Supplied sterile in peel-open packages. Intended for single procedure use.

RECEIVED

22 Dec 97 11 29

FDA/CDRH/ODE/CHG

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR Over-the-Counter Use

Judy Anderson for Doyle Cantt
(Division Sign-Off) Atling Branch Chief, ICDB
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K974774