K983771

NOV 1 2 1998

Special 510(k) Premarket Notification G.2
Strategy™ Coronary Wire Guide
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:	Strategy™ Coronary Wire Guide
Proposed Classification Name:	Wire, Guide, Catheter 21 CFR Part 870.1330 (74DQX)

Predicate Devices:

The Strategy™ Coronary Wire Guide has the same intended use, materials of construction, and technological characteristics as the Roadrunner™ RLTF Guide Wire and the ACS Hi-Torque Cross-It™ Guide Wire with Hydrocoat™ Coating.

Device Description:

The Strategy™ Coronary Wire Guide is used to facilitate delivery of a PTCA balloon catheter or other cardiovascular device into the cardiovascular system. The device will be constructed of stainless steel and platinum with hydrophilic coating. The Strategy™ Coronary Wire Guide outside diameter is 0.014-inch and will be available in 180 and 300 cm lengths with straight and J-curve distal tips. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

The Strategy™ Coronary Wire Guide is constructed using similar materials as the Roadrunner™ RLTF Guide Wire and the ACS Hi-Torque Cross-It™ Guide Wire with Hydrocoat™ Coating. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1998

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

Re: K983771
Trade Name: Strategy™ Coronary Wire Guide
Regulatory Class: II
Product Code: DQX
Dated: November 4, 1998
Received: November 5, 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

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
And Neurological Deveces
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983771

Device Name: Strategy™ Coronary Wire Guide

Indications for Use:

Intended for use in facilitating delivery of a PTCA balloon catheter or other cardiovascular device into the cardiovascular system.

(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)

Tuat. R for A. Doyle Gantt

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983771