

JUN 29 1998

K981906

Special 510(k) Premarket Notification  
PTA Balloon Catheter, D.C.#K981906  
COOK INCORPORATED

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**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  
June 25, 1998

**Device:**

Trade Name: None  
Proposed Classification Name: Catheter, Cardiovascular Balloon Type  
(79GBR)

**Predicate Devices:**

The COOK PTA balloon catheter is similar in terms of intended use, materials of construction, and technological characteristics to predicate devices reviewed as devices for transluminal percutaneous angioplasty of vessel lumens which are narrowed or obstructed.

**Device Description:**

The COOK PTA balloon catheter is an over-the-wire balloon catheter indicated for percutaneous transluminal angioplasty of lesions in peripheral arteries including iliac, renal, popliteal, infrapopliteal, femoral and ilio femoral and are also intended to treat obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device will be made with 5.0(6.0) French vinyl tubing compatible with an 0.035-inch guidewire. It will be supplied sterile, intended for one-time use.

**Substantial Equivalence:**

This 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. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

### **Test Data**

The balloon catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

- Tensile tests
- Flow rate tests
- Repeated balloon inflation tests
- Balloon burst tests
- Biocompatibility tests
- Animal tests to assess *in vivo* performance characteristics

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 a vascular PTA balloon.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. April Lavender  
Cook, Inc.  
925 South Curry Pike  
P.O. Box 489  
Bloomington, IN 47402

Re: K981906  
PTA Balloon Catheter  
Regulatory Class: II (two)  
Product Code: 74 LIT  
Dated: May 29, 1998  
Received: June 1, 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 (Pre-market 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 pre-market 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.

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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) 594-4648. 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" (21 CFR 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, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

