MAY 27 2003

K023937

K. 510 (K) SUMMARY

Submitted By:

Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular Incorporated
P.O. Box 529
Leechburg, PA 15656
Phone 724-845-8621
FAX 724-845-2848
November 14, 2002

Device:

Trade Name:	Cook Vascular SERPENTA™ Coronary Sinus Introducer System
Common/Usual Name:	Percutaneous Catheter Introducer
Proposed Classification Name:	Introducer, Catheter 21 CFR Part 870.1340 (74-DYB)

Device Description:

The Cook Vascular SERPENTA™ Coronary Sinus Introducer System consists of two Teflon (PTFE) introducer sheaths (7 Fr. and 10 Fr.) with varying shaped curves, two Teflon (PTFE) dilators (7 Fr. and 10 Fr.) two silicone Peel-Away introducer valves (D.C.# K010128), a hydrophilic coated guide wire with a torque handle, a 10cc plastic syringe and a stainless steel introducer needle. Some sets include a polyethylene obturator.

Indications for Use:

The intended use of Cook Vascular SERPENTA™ Coronary Sinus Introducer System is for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Vascular Incorporated. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510 (k) substantial equivalency.

Predicate Devices:
The Cook Vascular SERPENTA™ Coronary Sinus Introducer System is substantially equivalent to devices currently marketed as identified with respect to intended use, material composition, and method of operation.

Predicate Device	Manufacturer	510(k)
Cook Introducer	Cook Incorporated	Pre-amendment # A176790
Attain LDS 6216 Left Heart Delivery System	Medtronic	DC# K012130
Attain Access 6218 Left Heart Delivery System	Medtronic	DC# K012083
SafeSheath MSP (same as SafeSheath CSG)	Thomas Medical	DC# K003731

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2003

Cook Vascular Incorporated
c/o Mr. Thomas J. Kardos
Vice President, Regulatory Affairs
P.O. Box 529, Rt. 66 River Road
Leechburg, PA 1565-0529

Re: K023937
Trade Name: SERPENTA® Coronary Sinus Introducer System
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II (two)
Product Code: DYB
Dated: April 25, 2003
Received: April 28, 2003

Dear Mr. Kardos:

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.

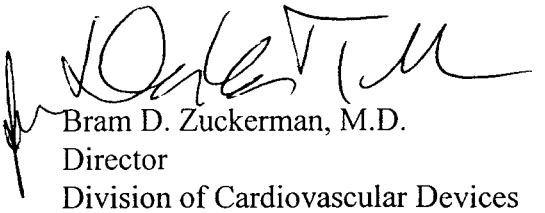
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023937

Device Name: SERPENTA™ Coronary Sinus Introducer System

Indications For Use:

The SERPENTA™ Coronary Sinus Introducer System is intended for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus. SERPENTA™ Coronary Sinus Introducer System is supplied sterile and intended for one time use

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023937

Perscription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)