K 061000

510(k) Summary

Submitted by:

MAY 10

Jim Ferguson
Quality Systems Manager
Cook Vascular, Incorporated
1186 Montgomery Lane
Vandergrift, Pa 15690
724-845-8621, XT 2227
April 10, 2006

Device:

Trade name:	Cook Vascular EVOLUTION Mechanical Dilator Sheath Set
Proposed Classification:	Dilator, Vessel, for Percutaneous Catheterization 870.1310, DRE

Predicate Devices:

The Cook Vascular EVOLUTION Mechanical Dilator Sheath Set is similar in terms of intended use, materials of construction and technology characteristics to predicate devices reviewed as devices for dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

Device Description:

The proposed device is a polypropylene dilator with a semi-threaded stainless steel tip. This stainless steel tip is used to dilate tissue surrounding an indwelling catheter or foreign object. In addition, an ergonomic handle to be used as a "drive mechanism" will be included. The device will be made with 7.0 and 9.0 French sizes. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

This device will be manufactured to specified process controls and a Quality Assurance program. This device will undergo packaging similar to the devices currently marketed and distributed by Cook Vascular. This device will undergo sterilization similar to the devices currently marketed and distributed. Being similar with respect to indication for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

Test Data:

The Cook Vascular EVOLUTION Mechanical Dilator Sheath Set was subjected to the flowing tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Buckling Test
2. Binding Test
3. Bond strength (Connector/gun)
4. Pull Testing (tip)
5. Handle Cycling Test
6. Device Performance

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 Dilator Sheath.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

Cook Vascular, Inc.
c/o Mr. Jim Ferguson, Jr.
Quality Systems Manager
1186 Montgomery Lane
Vandergrift, Pennsylvania 15690

Re: K061000
Trade/Device Name: EVOLUTION Mechanical Dilator Sheath Set
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: II
Product Code: DRE
Dated: April 10, 2006
Received: April 11, 2006

Dear Mr. Ferguson:

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 (240) 276-0115. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K061000

Device Name: EVOLUTION Mechanical Dilator Sheath Set

Indications for Use:

The Cook Vascular EVOLUTION Mechanical Dilator Sheath Set is for use in the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

(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 General, Restorative, and Neurological Devices

510(k) Number K061000

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 810 Subpart C)