

K974617

DEC 1 1998

**EndoVascular Instruments Inc.'s
Peripheral Vascular Dilator Premarket Notification
Summary Of Data**

1. Submitter:

Tom Kelly
Director of Engineering
EndoVascular Instruments, Inc.
2501 SE Columbia Way, Suite 150
Vancouver, Washington 98661-8038
Tel: (360) 750-1150
Fax: (360) 750-1101

2. Device Name

2.1 Classification: Panel 70, Class II, 870.4475
2.2 Common/Usual Name: (Surgical Vessel) Vascular Dilator
2.3 Proprietary Name: Peripheral Vascular Dilator

3. Predicate Device:

3.1 Cook, Inc.'s Dotter Transluminal Dilator
3.2 Pilling Weck's Amato Dilators

4. Intended Use:

The EndoVascular Instrument Peripheral Vascular Dilator is intended to be used to enlarge or calibrate a vessel

5. Device Description:

The vascular dilator is a catheter with smooth stainless steel tip(s) that enlarges the lumen of the artery and/or measures the caliber via the tip of the vessel. Access is either percutaneous (interventional through a sheath) or cut down (surgical, through an arteriotomy) procedure.

The vascular dilator is used over a guidewire and has tip(s) of increasing size to enlarge the lumen with each repeated pass or to measure the vessel size. Only an appropriately trained physician using sterile techniques uses the sterile device.

6. Substantial Equivalency Comparisons:

EVI's Peripheral Vascular Dilator is substantially equivalent to Cook, Inc.'s Dotter Transluminal Dilator and Pilling Weck's Amato Dilators, which are preamendment device.

6.1 Comparison of Physical Characteristics:

A comparison of physical characteristics of EVI's Peripheral Vascular Dilator to Pilling Weck's Amato Dilator indicates that they are substantially equivalent in materials;

**EndoVascular Instruments Inc.'s
Peripheral Vascular Dilator Premarket Notification
Summary Of Data**

construction; diameter and length dimensions, and configuration. The strength of the Vascular Dilator's joints and connections is equal to or greater than the Amato dilator.

6.2 Comparison of Physical Characteristics:

EVI's Vascular Dilator is substantially equivalent to Cook Inc.'s Dottering Set in intended use. Both dilators are used to dilate atheromas and to calibrate vessels. Results of tests indicated that the Vascular Dilator effectively enlarged the vessels and posed no new safety or efficacy issue in any of the tests.

7. Conclusions:

Comparison of EVI's Vascular Dilator to Cook's Dotter Dilator performance characteristics indicate that they are substantially equivalent. Comparison of EVI's Vascular Dilator and Pilling Weck's Amato Dilator physical characteristics indicates that they are substantially equivalent.



DEC 1 1998

Mr. Tom Kelly
Director of Engineering
EndoVascular Instruments, Inc.
2501 SE Columbia Way, Suite 150
Vancouver, WA 98661-8038

Re: K974617
Trade Name: Peripheral Vascular Dilator
Regulatory Class: II
Product Code: DRE
Dated: November 6, 1998
Received: November 9, 1998

Dear Mr. Kelly:

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

Page 2 - Mr. Tom Kelly

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
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Unknown

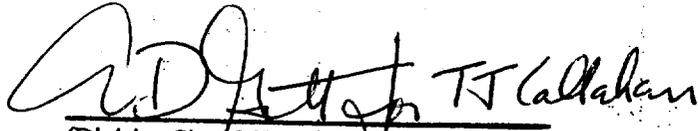
510(k) Number (if known): _____

Peripheral Vascular Dilator

Device Name: _____

Indications For Use:

The Endovascular Instrument Peripheral Vascular Dilator is intended to be used to enlarge or calibrate a vessel as an adjunctive procedure to other interventional procedures such as catheterization.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K974617

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

Concurrence of CDREH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____