K062474
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510(k) Safety and Effectiveness Summary

Date:	Feb. 23, 2006
Prepared By:	Cheryl Curry
Common/Usual Name:	Carotid Shunt
Proprietary Name:	Implantable Devices Shunt
Classification:	Class II 870.1200
Description:	A tapered shunt used to divert blood flow from the common carotid artery to the internal carotid during carotid endarterectomy.
Indications for Use:	Carotid Endarterectomy
Substantial Equivalence:	Sundt Shunt, Pruitt-Inhara Shunt, Smithwick Shunt, Javid Shunt, Vascuflo Shunt and Modified Carotid Shunt by Uresil Corp.
Conclusion:	The Implantable Devices Shunt is safe and effective for carotid endarterectomy.

NOV - 9 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2006

McPherson Enterprises, Inc.
c/o Mr. William E. McPherson
3851 62nd Avenue N. Suite A
Pinellas Park, EL 33781

Re: K062474
Smithwick Carotid Shunt
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (Two)
Product Code: DXC
Dated: August 22, 2006
Received: August 29, 2006

Dear Mr. McPherson:

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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Wichmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062474

Device Name: Smithwick Carotid Shunt
Models WR1409SB DWR1409SB
Models WR1409DB DWR1409DB

Indications For Use:

This device is used during carotid endarterectomies as a temporary conduit, to allow for blood flow between the common and internal carotid arteries.

Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuchner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062474