FEB 1 1999

K984183

POSSIS MEDICAL INC
9055 Evergreen Blvd. N.W.
Minneapolis, Minnesota 55433-8003 USA
(612) 780-4555
Fax (612) 780-2227

PERMA-PASS™ VASCULAR GRAFT
510(K) SUMMARY

NOVEMBER 1998

SUBMITTER'S INFORMATION	Possis Medical, Inc. 9055 Evergreen Boulevard N.W. Minneapolis, MN 55433 Tel: (612) 780-4555 Fax: (612) 780-2227
CONTACT	Primary Timothy J. Kappers Sr. Regulatory Affairs Associate Alternate James D. Gustafson Vice President of Quality Systems and Regulatory/Clinical Affairs
SUMMARY DATE	November 20, 1998
DEVICE TRADE NAME	Perma-Pass™ Vascular Graft
COMMON NAME	Vascular Graft
DEVICE CLASS	Vascular Graft prosthesis of less than 6 mm diameter (74DYF, 21 CFR 870.3450)
LEGALLY MARKETED PREDICATE DEVICE	IMPRA ePTFE Vascular Graft Straight; 5 mm x 50 cm K791810 IMPRA, Inc. 1625 West Third Street Tempe, Arizona 85281

DEVICE DESCRIPTION

The Perma-Pass™ Vascular Graft is manufactured from the following materials; polytetraflouroethylene (PTFE) resin, lubricant used as a manufacturing aid, and a black pigment used to create the orientation line. These grafts are available in a straight configuration with an internal diameter of 5mm, thin wall, and lengths sufficient to satisfy most vascular graft applications.

The Perma-Pass Graft is constructed from the same materials used in manufacturing the tubing for the Perma-Flow® Coronary Bypass Graft, manufactured by Possis Medical, Inc. and approved under HDE H970005 dated 30 April, 1998. These grafts are supplied in the same packaging as the Perma-Flow Graft and are packaged, labeled and sterilized in the same manner.

INTENDED USE

The Perma-Pass Graft is intended for bypass or reconstruction of occluded or diseased arterial blood vessels, or the creation of subcutaneous arteriovenous conduits for blood access. The Graft is intended for use as a vascular prosthesis only.

- Thinwall Perma-Pass Grafts are not indicated for blood access.

- Perma-Pass Grafts are not indicated for applications involving: pulmonary arteries; ascending aorta; coronary arteries; common, external, or internal carotid arteries; cerebral arteries; brachiocephalic trunk; cardiac veins; pulmonary veins; or the inferior or superior vena cava.

COMPARISON TO PREDICATE DEVICE:

Table 1 summarizes key technical characteristics and physical properties of the Perma-Pass Graft and the predicate device.

TABLE 1
Comparison of Technical Characteristics

	IMPRA Graft	Perma-Pass Graft
Materials	PTFE: No additives	PTFE: No additives
Markings	Longitudinal orientation	Longitudinal orientation
Clinical application	Bypass or reconstruction of occluded or diseased arterial blood vessels, vascular access and others	Bypass or reconstruction of occluded or diseased arterial blood vessels
Fabrication	Paste extrusion, expansion, sintering	Paste extrusion, expansion, sintering
Structure		
Configuration	Straight, isodiametric	Straight, isodiametric
Dimensions		
Length (all sizes)	50cm	70cm

	IMPRA Graft	Perma-Pass Graft
Internal diameter	5.17mm	5.01mm
Wall Thickness	0.420mm	0.453mm
Physical properties		
Pore volume	69%	67%
Internodal distance	Inner: 21μm Outer: 24μm	Inner: 21μm Outer: 21μm
Water entry pressure	276mmHg	309mmHg
Kink diameter	14mm	13mm
Pressurized burst strength	325kPa	381kPa
Tensile Strength		
Longitudinal	126N	121N
Circumferential	3.10N/mm	3.50N/mm
Suture retention strength		
Longitudinal	283g	535g
Oblique	285g	553g

NON-CLINICAL TESTS

Extensive testing of *in vitro,* functional, physical, and biocompatibility tests have been performed on the Perma-Pass Graft. These tests have shown that the Graft performs comparably to the predicate device. All performance results for the Graft and the predicate device exceed physiological requirements for the intended clinical use of the device. Where applicable, tests were conducted using USP or AAMI guidelines and standards. The results were acceptable in all cases.

CONCLUSION

The Perma-Pass Vascular Graft is a 5mm straight vascular prosthesis, intended as a permanent implant for bypass or reconstruction of occluded or diseased arterial blood vessels. The present 510(k) compares the Perma-Pass Graft to a legally marketed predicate device. The intended use, graft configuration, material, labeling, method of use, intended anatomical sites, and the target population of the Perma-Pass Graft are the same as those of the predicate device.

The Perma-Pass Graft is manufactured from PTFE, well known to the market with a long history of successful implantation in the human body. There are no known technological differences between the subject device and the predicate device. Extensive testing has shown the subject device is equivalent to the predicate device.

As summarized above, this 510(k) notification provides adequate information to support a determination of substantial equivalence between the Perma-Pass Graft and its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1999

Mr. Timothy J. Kappers
Sr. Regulatory Affairs Associate
Possis Medical, Inc.
9055 Evergreen Boulevard, N.W.
Minneapolis, MN 55433-8003

Re: K984183
Perma-Pass™ Vascular Graft, 5T Graft, Model 31451
Regulatory Class: III (Three)
Product Code: 74 DYF
Dated: November 20, 1998
Received: November 23, 1998

Dear Mr. Kappers:

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 (Premarket 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 premarket 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.

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

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PERMA-PASS™ VASCULAR GRAFT
INDICATION FOR USE STATEMENT

NOVEMBER 1998

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984183

Prescription only