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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K954848

FEB - 1 1996

Owner:

Meadox Medicals, Inc.
112 Bauer Drive
Oakland, NJ 07436
(201) 337-6126
Fax # (201) 337-5797

Contact Person:

Carolyn Tauber
Senior Regulatory Affairs Specialist

Submission Date:

Device Name:

HEMASHIELD® CARDIOVASCULAR GRAFTS:
HEMASHIELD® MICROVEL® Double Velour Knitted Vascular Grafts
HEMASHIELD® Woven Double Velour Vascular Grafts

Predicate Devices:

HEMASHIELD® CARDIOVASCULAR GRAFTS:
HEMASHIELD® Knitted MICROVEL® Double Velour Vascular Grafts
(PMA #P840029, approved April 26, 1989)
HEMASHIELD® Woven Double Velour Vascular Grafts
(PMA #P840029/S5, approved May 11, 1993)

Description of Device:

The HEMASHIELD® CARDIOVASCULAR GRAFTS are knitted and woven polyester grafts, impregnated with bovine collagen.

Intended Uses:

For use in the replacement or repair of arteries affected with aneurysmal or occlusive disease, which is substantially equivalent to the currently marketed devices.

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Substantial Equivalence: The proposed HEMASHIELD® MICROVEL® Double Velour Knitted and HEMASHIELD® Woven Double Velour Vascular Grafts have identical design, components, materials, intended use, and labeling to the currently marketed devices with PMA approval. The only difference between the proposed and the currently marketed devices is there are some modifications in the manufacturing process for the collagen component of the proposed devices. Testing has been performed which demonstrates that in spite of these modifications in the collagen manufacturing process, the proposed devices are substantially equivalent to the currently marketed PMA approved devices.

Product Testing: The following testing has been conducted on HEMASHIELD® MICROVEL® Double Velour Knitted and HEMASHIELD® Woven Double Velour Vascular Grafts to demonstrate the equivalency in safety and efficacy of these devices to their currently marketed PMA approved devices.

- Burst Strength - equivalent to marketed product
- Tensile Strength - equivalent to marketed product
- Suture Pull Out - equivalent to marketed product
- Wall Thickness - equivalent to marketed product
- Longitudinal Stretch - equivalent to marketed product
- Needle Penetration - equivalent to marketed product
- Crush Resistance - equivalent to marketed product
- Flexural Rigidity - equivalent to marketed product
- Integral Water Permeability - equivalent to marketed product
- Integral Water Permeability under load - equivalent to marketed product
- Strength of Collagen Bonding - equivalent to marketed product
- Shrinkage Temperature - equivalent to marketed product
- Glycerol Content - equivalent to marketed product
- Collagen Content - equivalent to marketed product
- Scanning Electron Micrographs - equivalent to marketed product

Biocompatibility Testing: Testing performed in accordance with ISO 9000 Standards indicates that the HEMASHIELD® Woven Double Velour and HEMASHIELD® MICROVEL® Double Velour Knitted Vascular Grafts with modifications in the manufacturing process for the collagen component are safe for their intended use and substantially equivalent in biocompatibility to the currently marketed PMA approved devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 1996

Ms. Carolyn Tauber
Senior Regulatory Affairs Specialist
Meadox Medicals, Inc.
112 Bauer Drive
Oakland, New Jersey 07436

Re: K954848
HEMASHIELD® MICROVEL® Double Velour Knitted and
HEMASHIELD® Woven Double Velour Vascular Grafts
Regulatory Class: II (two)
Product Code: 74MAL
Dated: October 20, 1995
Received: October 23, 1995

Dear Ms. Tauber:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for registration, listing of devices, good manufacturing practices, and 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulation.

Under Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA are required to conduct postmarket surveillance studies. FDA has

identified under Section 522(a)(1)(A) the device cleared for marketing by this letter as requiring postmarket surveillance.

Within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you are required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is attached.

Submit five (5) copies to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Suite 405 (HFZ-544)
1801 Rockville Pike
Rockville, Maryland 20852

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. You should not begin your postmarket surveillance study of this device until the protocol has been approved. Data generated under an unapproved protocol may not satisfy your obligation under section 522. Please note that you must continue to collect and report data needed to maintain compliance with Medical Device Reporting regulations (21 CFR 803).

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete and FDA approved postmarket surveillance study consistent with the protocol will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 U.S.C. 331 (q)(1)(C). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

If you have questions specifically concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

In addition, on August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirement of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

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

Enclosures

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