

SEP 12 2005

Special 510(k) – Device Modification  
Hemashield Platinum Woven Double Velour Vascular Grafts  
– Thoracoabdominal (TAAA) Graft Configuration  
August 22, 2005

## Summary of Safety and Effectiveness

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**General Provisions**

Trade Name:  
Hemashield Platinum Woven Double Velour TAAA graft configuration

Classification Name:  
Graft, Vascular, Synthetic / Biologic Composite

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**Name of Predicate Devices**

Hemashield Platinum Woven Double Velour Vascular Grafts

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**Classification**

Class II

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**Performance Standards**

Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act

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**Intended Use and Device Description**

The HEMASHIELD PLATINUM™ Vascular Graft is indicated for use in the replacement or repair of arteries affected with aneurysmal or occlusive disease. The prosthesis is also recommended for use in patients requiring systemic heparinization prior to, or during, surgery. The Hemashield Platinum WDV grafts are woven double velour vascular grafts impregnated with a highly purified collagen. The Hemashield Platinum WDV grafts minimize bleeding at implant and thereby eliminate the operative preclotting step, including cumbersome autoclave techniques. The collagen is gradually resorbed by the patient. The CONCENTRICRIMP® pleat and GUIDELINE® are also featured. In addition to collagen, the graft also contains glycerol as a softening agent.

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**Biocompatibility**

There have been no changes in materials or manufacturing process flow for this device modification. The Hemashield Vascular Graft product line has been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.

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**Summary of Substantial Equivalence**

The Hemashield Platinum WDV TAAA configuration has been tested and compared to the predicate devices. All data gathered demonstrate this device is substantially equivalent. No new issues of safety or efficacy have been raised.

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SEP 12 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Boston Scientific Corporation  
c/o Ms. Jennifer Bolton  
Manager, Regulatory Affairs  
Two Scimed Place  
Maple Grove, MN 55311-1566

Re: K052302  
Hemashield Platinum Woven Double Velour TAAA Graft Configuration  
Regulation Number: 21 CFR 870.3460  
Regulation Name: Vascular Graft Prostheses of 6MM and Greater Diameter  
Regulatory Class: Class II (two)  
Product Code: MAL  
Dated: August 22, 2005  
Received: August 24, 2005

Dear Ms. Bolton:

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.

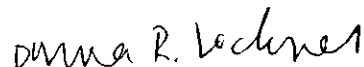
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


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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 (301) 594-4648. 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,



 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): K052302

Device Name: Hemashield Platinum Woven Double Velour TAAA graft configuration

Indications For Use:

The HEMASHIELD PLATINUM™ Vascular Graft is indicated for use in the replacement or repair of arteries affected with aneurysmal or occlusive disease. The prosthesis is also recommended for use in patients requiring systemic heparinization prior to, or during, surgery.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Dennis R. Kachner*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K052302