

OCT - 2 2001

## Section 5

### Summary of Substantial Equivalence

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**Summary of Modifications**

As shown previously in this submission, the Branch Graft Configurations is different from the rest of the Hemashield Gold Woven Double Velour Vascular Graft product line only in the 1-4 branch configuration in which the grafts are sewn.

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**Substantial Equivalence**

The modified vascular grafts have the following similarities to those which received previously received 510(k) concurrence:

- Identical indications for use
- Identical labeling
- Identical manufacturing processes
- Identical operating principle
- Incorporate identical materials
- Have the identical shelf-life (5 years)
- Are packaged and sterilized using identical packaging materials and processes

In summary, the Branch Graft configuration of the Hemashield Gold Woven Double Velour Vascular Graft product line described in this submission are equivalent to the predicate device.

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## Summary of Substantial Equivalence, Continued

### Summary of Design Control Activities

The design verification tests below are a combination of standard release tests and in-process functional tests conducted on the Hemashield Woven Double Velour Vascular Graft product line. Also included in this list are biocompatibility and shelf life tests conducted on Hemashield Woven Double Velour Vascular Grafts. There is no change to these tests or to their acceptance criteria for the Branch Graft line extension.

Test Performed		Acceptance Criteria
1	Visual Inspection – Stains	$\leq 0.05\text{mm}^2$
2	Visual Inspection – Foreign Matter	$\leq 0.03\text{mm}^2$
3	Water Permeability	Accept: if $\leq 4.0 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$ Reject: if $> 4.5 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$  Repeat test if $> 4.0$ and $\leq 4.5 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$ If re-test values are all $< 4.5 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$ then batch is acceptable.
4	Burst	$> 399.9 \text{ lb/inch}^2$
5	Crimp	12.0 turns/inch – circular
6	Usable Length	Main Graft – $45 \pm 5\text{cm}$ Head Branches – $17.5 \pm 2.5\text{cm}$ Perfusion Branch – $22.5 \pm 2.5\text{cm}$
7	Inner Diameter	$\leq 10.0 \text{ mm}$ sizes; nominal diameter $\pm 0.5 \text{ mm}$ $> 10.0 \text{ mm}$ sizes; nominal diameter $\pm 1.0 \text{ mm}$
8	Visual Inspection – Sewing	No sewing defects
9	Air Permeability	$\leq 24.5 - 43.5 \text{ l/m}$ (depending upon size)
10	<b>Pyrogenicity:</b> Rabbit Pyrogen	Pass
11	<b>Acute Systemic Toxicity:</b> Acute Systemic Injection	Pass
12	<b>Irritation:</b> Acute Intracutaneous Reactivity	Pass
13	<b>Hemocompatibility:</b> Hemolysis	Pass
14	<b>Cytotoxicity:</b> ISO L929 MEM Elution	Pass
15	<b>Mutagenicity:</b> Ames Test (Saline extract)	Pass

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## Summary of Substantial Equivalence, Continued

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16	<b>Subchronic toxicity: 14 day IV injection in rats</b>	Pass
17	<b>Implantation: ISO Muscle Implantation with histopathology (2 week)</b>	Pass
18	<b>Implantation: ISO Muscle Implantation with histopathology (12 week)</b>	Pass
19	<b>Physiochemical</b>	Pass
20	<b>Shelf Life Testing</b>	Meets Product Specification after aging

All testing was done with standard test methods for these parameters. All testing showed the Branch Graft configuration is substantially equivalent to the predicate device. ***No new issues of safety or efficacy were raised. A declaration of conformity with design controls is included in Attachment 3.***

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**510(k)  
Statement**

A 510(k) Summary and Certification can be found in Attachment 4.

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**Truthful and  
Accuracy  
Statement**

A certification of Truthful and Accuracy can be found in Attachment 5.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT - 2 2001

Ms. Jennifer Bolton  
Senior Regulatory Affairs Specialist  
Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760-1537

Re: K012952  
Hemashield Gold Woven Double Velour Vascular Graft-Branch Graft  
Regulation Number: 21 CFR 870.3460  
Regulation Name: Vascular graft prosthesis of 6 millimeters and greater diameter.  
Regulatory Class: II  
Product Code: DSY  
Dated: August 31, 2001  
Received: September 4, 2001

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.

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

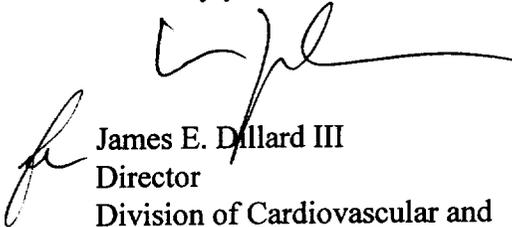
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications For Use

510(k)  
Number  
(if known)

Unknown K012952

Device  
Name:

Hemashield Gold Woven Double Velour Vascular Graft  
– Branch Graft

Indications  
for Use

The Hemashield Gold™ Woven Double Velour 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.

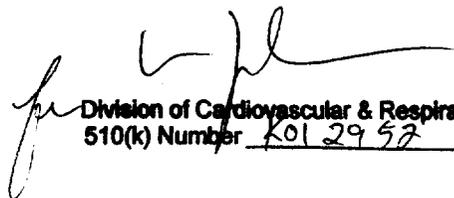
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K012952