JAN 6 2006

K052964

510(k) SUMMARY

Date Prepared: January 3, 2005

Device Owner:
Boston Scientific Corporation
2 Scimed Place
Maple Grove, MN 55311-1566

Contact Personnel: Katie Gerbensky
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Trade Name(s):
EXXCEL™ and EXXCEL™ *Soft* ePTFE Vascular Grafts
MICROVEL™DOUBLE VELOUR Knitted Vascular Grafts
WOVEN DOUBLE VELOUR Woven Vascular Grafts
COOLEY™ VERI-SOFT™ Woven Vascular Grafts

Device Generic Name: Vascular Graft Prosthesis

Classification: According to Section 513 of the Federal Food, Drug and Cosmetic Act, these devices are Class II, Performance Standards.

Predicate Devices:
EXXCEL™ and EXXCEL™ *Soft* ePTFE Vascular Grafts
MICROVEL™DOUBLE VELOUR Knitted Vascular Grafts
WOVEN DOUBLE VELOUR Woven Vascular Grafts
COOLEY™ VERI-SOFT™ Woven Vascular Grafts

Device Description:
EXXCEL™ & EXXCEL™ Soft ePTFE Vascular Grafts:
EXXCEL™ & EXXCEL™ Soft ePTFE Vascular Grafts are synthetic vascular grafts constructed of extruded, expanded polytetrafluoroethylene (ePTFE). They are available in various configurations, with the following features:

- EXXCEL™ grafts have a unique cross-helical PTFE yarn wrap to enhance mechanical strength, minimize kinking and increase suture retention strength.
- EXXCEL™ Soft grafts are ePTFE grafts without a yarn wrap, that possess enhanced handling characteristics.
- Straight grafts (available in EXXCEL™ & EXXCEL™ Soft)have a uniform diameter throughout their length.
- Short Taper and Step grafts (available in EXXCEL™ & EXXCEL™ Soft) are designed to have the arterial anastomosis of vascular access procedures created

with the smaller diameter end to reduce the risk of steal syndrome.

- Externally Supported grafts (available only in EXXCEL™ Soft) have a removable, continuous spiral support coil to increase compression resistance and to minimize kinking.
- Centrally Supported grafts (available in EXXCEL™ & EXXCEL™ Soft) have a non-removable, continuous spiral support coil located in the center of the graft's length, to provide additional kink and compression resistance for grafts implanted in a looped configuration for vascular access.

All EXXCEL™ & EXXCEL™ Soft ePTFE Vascular Grafts feature a GUIDELINE™ Stripe to facilitate proper graft alignment.

MICROVEL™ KNITTED DOUBLE VELOUR:
This seamless knitted double velour polyester graft incorporates a lower inner pile for minimal luminal compromise and a higher outer pile to promote perigraft tissue adherence. This graft is soft, pliable, and complies with ease to the host vessel. This graft features CONCENTRICRIMP™ Pleats, which assist in proper length adjustment of the prosthesis and maintenance of an open lumen at the anastomosis, and throughout the entire graft. There is a GUIDELINE™ Stripe to facilitate proper graft alignment. The knitted velour construction of this graft is preferred by surgeons in abdominal and peripheral procedures. Not recommended for thoracic procedures.

WOVEN DOUBLE VELOUR :
This seamless woven polyester graft incorporates a velour inner pile to promote attachment of the pseudointima and a velour outer pile to promote perigraft tissue adherence. The unique woven double velour construction provides soft and supple handling characteristics, while maintaining a low porosity. CONCENTRICRIMP™ Pleats help in proper length adjustment of the prosthesis and maintenance of an open lumen at the anastomosis, and throughout the entire graft, while the two GUIDELINE™ Stripes help provide greater assurance of proper graft alignment. The Woven Double Velour graft is suitable for use in thoracic, abdominal and peripheral procedures.

COOLEY™ VERI-SOFT™:
The COOLEY™ VERI-SOFT™ graft is tightly woven polyester to maintain a low, controlled porosity level for minimal blood loss and high burst strength. This unique design offers significant advantages to heparinized patients or to those with rare blood types or coagulopathies. The soft texture provides a supple graft with enhanced healing characteristics. CONCENTRICRIMP™ Pleats resist kinking, reduce stress on the suture line and assist in proper length adjustment. The intrawoven GUIDELINE™ Stripe aids in graft alignment. The COOLEY™ VERI-SOFT™ woven graft is suitable for use in thoracic and abdominal procedures.

Indications for Use:

EXXCEL™ and EXXCEL™ *Soft* ePTFE Vascular Graft:
Standard Wall EXXCEL™ & EXXCEL™ *Soft* ePTFE Vascular Grafts are designed to repair or replace peripheral arteries (Iliac, Femoral, Popliteal, Infrageniculate Vessels, Axillary, Renal) and to provide vascular access. Thin Wall EXXCEL™ *Soft* ePTFE Vascular Grafts are designed to repair or replace peripheral arteries (Iliac, Femoral, Popliteal, Infrageniculate Vessels, Axillary, Renal). NOTE: Insufficient data is available on which to base any conclusions regarding the use of the Thin Wall EXXCEL™ *Soft* ePTFE Vascular Grafts for vascular access procedures.

MICROVEL™DOUBLE VELOUR Knitted Vascular Grafts, WOVEN DOUBLE VELOUR and COOLEY™ VERI-SOFT™ Woven Vascular Grafts:
The Microvel Double Velour, Woven Double Velour and Cooley Veri-Soft Grafts are indicated for use in the replacement or repair of arteries affected by aneurysmal or occlusive disease (Descending Thoracic Aorta, Abdominal Aorta, Axillary, Iliac, Femoral, Popliteal, Renal).

Technological Characteristics, Safety and Performance: No changes have been to any device attribute. This 510(k) clarifies the indications for use statement by indicating the specific arteries the devices are indicated to repair or replace.

Conclusion:

The above mentioned devices are safe and effective for their intended uses since the only change made to these already cleared devices is the addition of a listing of arteries in which the devices have a safe history of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Boston Scientific Corporation
c/o Ms. Katherine Gerbensky
Specialist, Regulatory Affairs, Vascular Surgery
Two Scimed Place
Maple Grove, MN 55311-1566

Re: K052964
Standard Wall Exxcel™ and Exxcel™ Soft ePTFE Vascular Grafts
Microvel™ Double Velour Knitted Vascular Graft
Woven Double Velour Vascular Grafts
Cooley™ Veri-Soft™ Woven Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis of Less than 6MM Diameter
Regulatory Class: Class II
Product Code: DSY
Dated: December 15, 2005
Received: December 15, 2005

Dear Ms. Gerbensky:

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

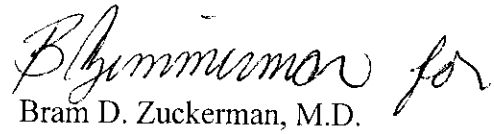
be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K052964 (covers vascular grafts previously cleared under K955460, K960766, K962433, K810845, K820696)

Device Name: Standard Wall Exxcel™ and Exxcel™ Soft ePTFE Vascular Grafts
Microvel™ Double Velour Knitted Vascular Graft
Woven Double Velour Vascular Grafts
Cooley™ Veri-Soft™ Woven Vascular Graft

Indications For Use: The Standard Wall Exxcel™ and Exxcel™ Soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries (Iliac, Femoral, Popliteal, Infrageniculate Vessels, Axillary, Renal) and to provide vascular access.

Thin Wall Exxcel™ soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries (Iliac, Femoral, Popliteal, Infrageniculate Vessels, Axillary, Renal).

The Microvel Double Velour, Woven Double Velour and Cooley Veri-Soft Grafts are indicated for use in the replacement or repair of arteries affected by aneurysmal or occlusive disease (Descending Thoracic Aorta, Abdominal Aorta, Axillary, Iliac, Femoral, Popliteal, Renal).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052964