# 510(k) Summary per 21 CFR §807.92

**Submitter's Name and Address**  
Boston Scientific Corporation (BSC)  
Two Scimed Place  
Maple Grove, MN 55311

**Contact Name and Information**  
Name: Maureen Montbriand  
Title: Regulatory Affairs Specialist  
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**Date Prepared**  
June 23, 2004

**Proprietary Name(s)**  
PTFE Felts and Pledgets

**Common Name**  
Intracardiac patch or pledget made of polytetrafluoroethylene

**Product Code**  
DXZ

**Classification of Device**  
Class II, 21 CFR Part 870.3470

**Predicate Device**  
PTFE Felts and Pledgets (Preamendment devices)

**Device Description**  
The PTFE Felts and Pledgets are manufactured from 100% polytetrafluoroethylene fibers. The felt is purchased from an outside supplier in bulk, which is then heat set, scoured and cut into squares, offering two sizes, or punched into oval, round, square or rectangular pledgets. The Felts have a nominal thickness of 1.245mm (0.049”). The Pledgats have a nominal thickness of either 0.99mm (0.039”) or 1.245mm (0.049”) depending upon size.

**Intended Use of Device**  
**Felts:** Indicated for Ventricular aneurysmectomy; tissue prosthesis, and suture buttressing.

**Pledgets:** Indicated for Tissue, prosthesis, and suture buttressing.

**Summary of Substantial Equivalence**  
The PTFE Felts and Pledgets have been tested. All data gathered has demonstrated that the device is Substantially Equivalent to the predicate device. No new issues of safety and efficacy have been raised.
Boston Scientific Corporation  
c/o Ms. Maureen Montbriand  
Regulatory Affairs Specialist  
Two Scimed Place B220  
Maple Grove, MN 55311-1566  

Re: K041716  
PTFE Felts and Pledgets  
Regulation Number: 21 CFR 870.3470  
Regulation Name: Intracardiac patch or pledget  
Regulatory Class: Class II  
Product Code: DXZ  
Dated: June 23, 2004  
Received: June 24, 2004  

Dear Ms. Montbriand:

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 (301) 594-4646. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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

<table>
<thead>
<tr>
<th>510(k) Number (if known)</th>
<th>Preamendment device</th>
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Prescription Use **X** AND/OR Over-The-Counter Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Cardiovascular Devices

510(k) Number K041716

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