K971139

JUN 25 1997

510 (k) Summary Of Safety And Effectiveness

Sponsor:	Boston Scientific Corporation One Scientific Place Natick, MA 01760-1537
Contact Person:	Lorraine M. Hanley Manager, Regulatory Affairs or Carol J. Holloway Regulatory Affairs Specialist
Submission Date:	March 24, 1997
Common/Usual Names:	Bone Anchor System
Trade/Proprietary Name:	TBD
Device Classification and Name:	Boston Scientific Corporation believes the proposed device combines devices classified as Class II: • CFR 888.3040; Smooth or threaded metallic bone fixation fastener; Procode: 87 HWC CFR 878.5000; Nonabsorbable poly surgical suture; Procode: 79 GAW
Substantial Equivalence:	The proposed devices are *Substantially Equivalent* to the predicate currently marketed devices indicated for use as a Bone Anchor System intended for soft tissue support.
Product Testing:	The proposed devices have been tested and compared to thepredicate devices. The results indicate that the proposed devices are *Substantially Equivalent* to the predicate devices in terms of performance characteristics tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol J. Holloway
Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

JUN 25 1997

Re: K971139
Trade Name: Bone Anchor Systems
Regulatory Class: II
Product Codes: MBI and HWC
Dated: March 24, 1997
Received: March 28, 1997

Dear Ms. Holloway:

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 (for the indications for use stated in the enclosure) to 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). 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 (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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug

Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Mary A Schroeder MS, PT

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K971139

Device Name:

Bone Anchor Systems

Indications For Use:

The proposed Bone Anchor System is intended for use in procedures that require placement of a bone anchor for the purpose of soft tissue reinforcement and support inclusive of, but not limited to, suspending suture/sling for the treatment of urinary stress incontinence attributable to hypermobility and/or intrinsic sphincter deficiency such as: Pubourethral, Urethrovesical, Pubovaginal, and Bladder Neck Support/Stabilization; Urethral and Vaginal Prolapse Repair; and Reconstruction of the Pelvic Floor

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____
(Per 21 CFR 801.109)

Marie A Schroeder, MS, PT for CMW

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971139