3/5/99

K990295

Boston Scientific
MICROVASIVE

Microvasive Urology

Section V. 510(k) SUMMARY of Safety and Effectiveness

Sponsor:	Boston Scientific/ Microvasive One Scientific Place Natick, MA 01760-1537
Contact Person:	Lorraine Hanley Divisional Manager, Regulatory Affairs
Submission Date:	January 28, 1999
Common/Usual Name:	Bone anchor
Trade/Proprietary Name:	TBD
Device Classification and Name:	Class II: CFR 888.3040; smooth or threaded metallic bone fixation fastener
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 sutures and/or placement of a 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.
Substantial Equivalence:	The proposed device is substantially equivalent to the predicate legally marketed devices indicated for use as Bone Anchor Systems intended for soft tissue support.
Product Testing:	The proposed device has been tested and results compared to the predicate devices. The results show that the proposed device is substantially equivalent to the predicate devices in terms of the performance characteristics that were tested.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

Ms. Christine E. Nichols
Senior Regulatory Affairs Specialist
Boston Scientific Corporation/Microvasive
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K990295
Trade Name: Bone Anchor System (BAS) III
Regulatory Class: II
Product Codes: MBI and HWC
Dated: January 28, 1999
Received: January 29, 1999

Dear Ms. Nichols:

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,

Russell P. Pazen

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

Section I-C. Indication For Use Statement

510(K) Number: K990295

Device Name: **Bone Anchor System III**

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 sutures and/or placement of a 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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990295

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