

APR 26 2000

K993630

510(k) Summary of Safety and Effectiveness

(1) **Submitter's name:** Encore Orthopedics, Inc.
Submitter's address: 9800 Metric Blvd, Austin, TX 78758
Submitter's telephone number: 512) 834-6237
Contact person: Debbie De Los Santos
Date summary prepared: October 14, 1999

(2) **Trade or proprietary device name:** BioLok® Screw
Common or usual name: Bone Fixation Screw
Classification name: Class II

(3) **Legally marketed predicate device:** Bio Interference Screw (Arthrex)
BioScrew (Linvatec)

(4) **Subject device description:**

The BioLok® Screw is a cannulated, sterile, single-use bone screw made of an absorbable polymer similar to that used in bioabsorbable suture and will gradually be absorbed into the body. The BioLok® Screw is manufactured from a mixture of Tri-Calcium Phosphate (TCP and poly (L-lactide) (PLLA).

(5) **Subject device intended use:**

The BioLok® Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures where the surgeon:

- places the graft in tibial and/or femoral tunnels; and
- inserts screws between the tunnel wall and graft to hold the graft in place.

The BioLok® Screw is used to provide interference fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

The BioLok® Screw is used to provide interference fixation during femoral and/or tibial fixation in ACL reconstruction using a soft tissue graft (semi-tendonosis gracilis).

(6) **Technological characteristics:**

The BioLok® Screw has the same technological characteristics (i.e., design and material) when compared to the predicate devices.

(7) **Performance data:**

Test results confirm that this composite has the requisite strength over time to provide early and sustained fixation of the graft. Pull out test results compare favorably with the predicate devices.

(8) **Basis for substantial equivalence:**

The BioLok® Screw is equivalent in design, materials and indications to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2000

Ms. Debbie De Los Santos
Regulatory/Clinical Specialist
Encore Medical Corporation
9800 Metric Boulevard
Austin, Texas 78758

Re: K993630
Trade Name: BioLok® Screw
Regulatory Class: II
Product Code: HWC
Dated: February 4, 2000
Received: February 7, 2000

Dear Ms. Los Santos:

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 control provisions of the Act. The general control 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.

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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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


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

Enclosure

510(k) Number (if known): K 993630

Device Name: BioLok® Screw™

Indications For Use:

BioLok® Screw

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. Kochner
(Division Supervisor)
Director, Office of Restorative Devices
510(k) number K993630

Prescription Use Yes
(per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)_