SEP 2 3 1999

K992367

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI X FIX® DynaFix® System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Jon Caparotta, RA Manager
Electro-Biology, Inc.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person:
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Date prepared: July 14, 1999

2. **Proprietary Name:** EBI X FIX® DynaFix® System – HA Coated Bone Screws
Common Name: External Fixation Bone Screws
Classification Name/Code: Pin, Fixation, Threaded (888.3040)/JDW

3. **Predicate or legally marketed devices that are substantially equivalent:**

   - Orthofix® External Fixation Screw with Hydroxapatite Coating-Orthofix Srl

4. **Description of the device:** The bone screws have a tapered thread diameter and are available in a variety of diameters and lengths in both cortical and cancellous thread patterns. The screws will be available with and without the additional proprietary hydroxapatite surface coating on the threads, and will be sold sterile and nonsterile. The coating has been shown to enhance fixation at the pin-bone interface and to reduce the incidence of pin loosening. Furthermore, osseointegration with direct contact between the bone and the screw thread was seen on histologic examination.

   Intended Use: The EBI X FIX® DynaFix® System Hydroxyapatite (HA) Coated Screws are intended for use in association with the external fixation of bone.

5. **Materials:** The HA Coated bone screws are manufactured from stainless steel, 316L per ASTM F138. The HA coating is applied by a proprietary process according to Device Master File MAF-339 and ASTM F 1185.

6. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the HA coated bone screws and other currently marketed bone screws since the addition of a HA coating does not adversely affect the use of the bone screws. The coated screws underwent biocompatibility, fatigue, and effectiveness testing to determine if the device was safe and effective. It is substantially equivalent* to the predicate devices in design and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

Mr. Jon Caparotta
Manager, Regulatory Affairs
Electro-Biology, Inc.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K992367
Trade Name: EBI X FIX® DynaFix® System Hydroxyapatite (HA) Coated Bone Screws
Regulatory Class: II
Product Code: HWC
Dated: July 14, 1999
Received: July 15, 1999

Dear Mr. Caparotta:

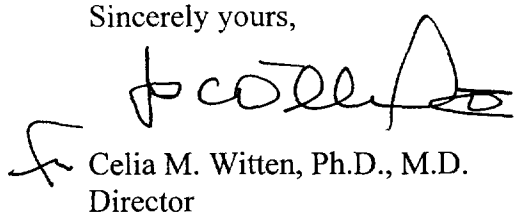
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



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

K992367

Statement of Indications for Use:

The EBI X FIX DynaFix® Hydroxyapatite® (HA) Coated Screws are intended for use in external fixation for the treatment of bone conditions including limb lengthening, corrective osteotemies, arthrodesis, fracture fixation, acute or gradual multiplanar correction and other bone conditions amenable to treatment by use of the external fixation modality.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992367

Prescription Use X
(Per 21 CFR 801.109)