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SECTION III

K981483

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness for the EBI DFS® Joint Fixator is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. Submitter:

Electro-Biology, Inc.
6 Upper Pond Road
Parsippany, NJ 07054

2. Date Prepared:

January 7, 1998

3. Official Correspondent:

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Contact Person:

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3. **Proprietary Name:**

EBI DFS® Joint Fixator

Common Name:

External Fixation Device

Classification Name:

Single Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030.

4. **Predicate or Legally Marketed Devices:**

Orthofix Elbow Fixator – Orthofix Inc.

5. **Description of Device:**

The **EBI DFS® Joint Fixator** is a line extension of the currently marketed EBI XFIX DynaFix Fixation System. The EBI DFS® Joint Fixator is unilateral in design and is therefore available in both left and right configurations. The major components of the **EBI DFS® Joint Fixator** are as follows:

- DFS® Telescoping Arm
- DFS® Dual Locking Connector Component
- DFS® Inner Body Female Rotation Component
- Central Elbow Disc
- Precision Dual Locking Connector Component
- Precision Inner Body Female Rotation Component
- Precision Telescoping Stem

Please note: The DFS® Telescoping Arm, DFS® Dual Locking Connector Component, DFS® Inner Body Female Rotation Component, Precision Inner Body Female Rotation Component, Precision Dual Locking Connector and Precision Telescoping Stem are also the components of the currently marketed EBI XFIX DynaFix Fixation System.

The **Central Elbow Disc** is comprised of the following components:

- Elbow U-Connector
- Elbow Rings (Outer and Inner)
- Elbow Distractor
- Optional Stopping Mechanisms

The **Elbow U-Connector** employs a locking set screw for attachment to the inner ring of the Central Elbow Disc. The Elbow U-Connector is designed to lock the movement of the outer Elbow Ring relative to the inner Elbow Ring. The outer Elbow Ring employs a male adapter with a threaded hole for attachment to the Distraction/Compression mechanism employed by the Elbow Distractor. A polyethylene bushing is placed between the outer and the inner ring to provide ease of rotation of the rings relative to each other.

The optional **Stopping Mechanism**, which is attached to the inner ring via a locking set screws, limits the motion of the outer and inner rings relative to each other, thereby, limiting joint movement. The optional Stopping Mechanisms can be positioned around the ring to provide optimal joint fixation.

The **Elbow Distractor** allows attachment of the DFS® Inner Body Female Rotation Component on one side and the Elbow ring on the other side. One side of the Elbow Distractor employs a male adapter for attachment to the

female adapter of the DFS® Inner Body Female Rotation Component. The other side of the Elbow Distractor employs a female adapter for attachment to the male adapter of the Elbow Ring. The male adapter of the Elbow Distractor is connected to the female adapter of the DFS® Inner Body Female Rotation Component at an angle to provide optimal fixation of bone screws in the bone. During surgery the distractor mechanism allows either distraction or compression of the articular surfaces for optimal treatment of the joint condition.

The Elbow Distractor, Elbow rings and the Elbow U-Connector of the Central Elbow Disc would be available in a range of sizes, for use with the components of the currently marketed standard, small and extra small EBI XFIX DynaFix Fixation System, to address patients with varying bone size requirements.

The components of the **EBI DFS® Joint Fixator** are fabricated from the following materials, which conform to the requirements specified in the American Society of Testing and Materials (ASTM) standards:

- Stainless steel (ASTM Standards A582, A582M-95A and ASTM F899)
- Aluminum alloy Al 6061-6 (ASTM B221)
- Delrin (ASTM D4181POMILL)

6. **Intended Use:**

The **EBI DFS® Joint Fixator** is intended for use in upper extremity treatment of bone and soft tissue conditions and other bone conditions amenable to treatment by use of the external fixation modality. Possible applications include:

a) fracture dislocation with ligamentos instability;
b) comminuted intra-articular fracture; and
c) post traumatic reconstruction for joint stiffness.

7. **Substantial Equivalence:**

The **EBI DFS® Joint Fixator** is substantially equivalent to the following predicate device:

Orthofix Elbow Fixator – Orthofix Inc.

The features of the **EBI DFS® Joint Fixator** are substantially equivalent to the features of the competitive device.

Substantial equivalence of the **EBI DFS® Joint Fixator** to the currently marketed Orthofix Elbow Fixator is demonstrated as follows:

- The components of the **EBI DFS® Joint Fixator** are fabricated from the same material as the components of the currently marketed Orthofix Elbow Fixator.

- The **EBI DFS® Joint Fixator,** like the predicate Orthofix Elbow Fixator, minimizes trauma to anatomical structures by controlling flexion and extension capabilities of the elbow. In addition, the **EBI DFS® Joint Fixator** would be utilized for the treatment of the wrist joint.

- The **EBI DFS® Joint Fixator** and the currently marketed Orthofix Elbow Fixator are both indicated for fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality.

- The **EBI DFS® Joint Fixator** like the currently marketed Orthofix Elbow Fixator employs bone screw clamps for accommodating bone screws affixed to the bone.

- The Central Elbow Disc component of the **EBI DFS® Joint Fixator** like the currently marketed Orthofix Elbow Fixator provides controlled movements of the joint.

- The **EBI DFS® Joint Fixator** like the currently marketed Orthofix Elbow Fixator employs a distractor mechanism that is initially used to disimpact the articular surfaces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 1998

Mr. Jon Caparotta
Manager, Regulatory Affairs
Electro-Biology, Inc.
6 Upper Pond Road
Parsippany, New Jersey 07054

Re: K981483
Trade Name: EBI DFS® Joint Fixator
Regulatory Class: II
Product Code: KTT
Dated: April 23, 1998
Received: April 24, 1998

Dear Mr. Caparotta:

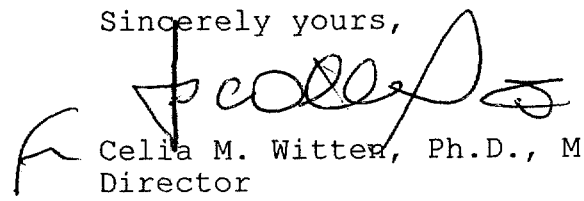
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4659. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
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Radiological Health

Enclosure

SECTION IV

K981483

STATEMENT FOR INDICATIONS FOR USE

The **EBI DFS® Joint Fixator** is intended for use in upper extremity treatment of bone and soft tissue conditions and other bone conditions amenable to treatment by use of the external fixation modality. Possible applications include:

1. fracture dislocation with ligamentos instability;
2. comminuted intra-articular fracture; and
3. post traumatic reconstruction for joint stiffness.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981483