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510(k) SUMMARY
Orthofix Dynamic Axial Fixation System
December 21, 1995

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87 and the SMDA.

1. **Submitter of 510(k)**

Robert L. Sheridan (Consultant)
Vice President, Device Evaluation
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Telephone: (301)770-9590
Facsimile: (301)770-9584

2. **Name of Device**:

A. Trade/Proprietary Name:

Orthofix® Modulsystem

B. Common/Usual Name:

Orthofix Dynamic Axial Fixation System

C. Classification Name:

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040).

3. **Sponsor/Manufacturer**:

ORTHOFIX Srl
Via delle Nazioni 9
37012 Bussolengo (VR), Italy

Attention: Rolando Stanghellini, Director of Quality Assurance

Telephone: 011-39-45-6767030
Facsimile: 011-39-45-6767135

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4. **Reason for Submitting the 510(k)**

The components of the Orthofix Dynamic Axial Fixation System described in this submission have all entered legal distribution in the U.S. as a result of the U.S. Food and Drug Administration's (FDA's) clearance of premarket notification K831576. Premarket notification [510(k)] K831576 was submitted to FDA on behalf of Orthofix by Electro-Biology Inc., (EBI), of Parsippany, New Jersey. All of the components described in this submission that were previously distributed in the U.S. by EBI, using the Orthofix brand name, were manufactured by Orthofix. The distribution agreement between Orthofix and EBI expired this year, and Orthofix began distributing these same devices through its own wholly owned subsidiary, Orthofix Inc., located in Richardson, Texas.

Orthofix submitted this application to notify FDA of the change in distributors and, thus, to clarify the FDA record.

5. **Device Description**

The Orthofix Dynamic Axial Fixation System, like most external fixation systems, includes various frames, bars, pin clamps, pins, accessories and instruments. The pin clamps enable the frame to be coupled to bone by securing the pins for the intended use. The various components within the system are necessary so that the physician can effectively treat diverse kinds of hard tissue maladies that arise due to differences in the anatomical location and the state of the soft tissues and bone, as well as any peculiarities specific to the individual case.

6. **Intended Use**

The intended use of the Orthofix Dynamic Axial Fixation System is unchanged from that previously stated in the original 510(k), K831576. That is, the intended use remains:

> "This product is a unilateral external fixation device, which is intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality."

7. **Substantial Equivalence**

A listing of all components distributed by Orthofix, Inc. was provided in the submission. A separate listing of all components manufactured by Orthofix and previously distributed by EBI was provided. Additionally, a list delineating the similarities and differences between the two listings was also provided. All differences were outlined in the submission. Additional components added to the Orthofix Dynamic Axial Fixation System since the expiration of the distribution agreement with EBI, were described. They have the same intended use and design characteristics as the components distributed by EBI and are consistent with the original 510(k) K831576.

The manufacturing of Orthofix Dynamic Axial Fixation System components has not been affected by the change in distributors. Further, as stated above, the intended use of the system is unchanged from that previously stated in the original 510(k), K831576.

Labeling for the system remains virtually the same, except for removal of the name "EBI" from all labeling and the issuance of labeling associated with the components marketed subsequent to the expiration of the distribution agreement with EBI. Brochures for the components distributed by Orthofix, Inc. were provided. For purposes of comparison, each Orthofix brochure was immediately followed by the corresponding brochure previously distributed by EBI. Instruction manuals or surgical instructions ("Operative Technique") were, also, provided. These publications provide operative recommendations for clinical use of the Orthofix system.

In conclusion, since the Orthofix Dynamic Axial Fixation System itself remains unaffected by the change in distribution practice, the device is substantially equivalent to itself. The information provided in this 510(k) demonstrates that the components distributed by Orthofix Inc. are identical to the Orthofix components previously distributed by EBI Further, none of the components added following the expiration of the distribution agreement with EBI represent changes which could significantly affect the safety or effectiveness of the device and do not alter the substantial equivalence of the system.