K973944

DEC 19 1997

510(k) SUMMARY[1]
Orthofix® Femoral Nailing System
October 14, 1997

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® Femoral Nailing System

B. Common/Usual Name:

Femoral Nailing System

C. Classification Name:

"Intramedullary Fixation Rod" (21 CFR 888.3020).

3. **Sponsor/Manufacturer:**

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

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[1] Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer 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)

Attention: Rolando Stanghellini, Director of Quality Assurance

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

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

We are submitting this document on behalf of our client, Orthofix Srl. (Orthofix), of Bussolengo, Italy. We are hereby notifying you of Orthofix's intention to commercially distribute its Femoral Nailing System for the first time in the U.S. Orthofix currently distributes a comparable nailing system for the tibia, Tibial Nailing System (K961027). Like our tibial nailing system and predicate devices our femoral nailing system includes a series of nails of varying diameters and lengths, locking screws and end caps, as well as the instruments and accessories used in their implantation and removal.

5. **Device Description**

The Orthofix femoral nail is manufactured from surgical grade stainless steel. The nail is available in five diameters, 9, 10, 11, 12 and 13 mm and varying lengths. The nails have two proximal and two distal locking holes. The screws are also manufactured from surgical grade stainless steel. They have a self tapping thread and are available in varying lengths. End caps are provided which screw into the nail's proximal end, preventing tissue ingrowth and allowing for easier explantation. The end caps are also manufactured from surgical grade stainless steel.

The system includes various instruments and accessories used during the implantation and removal of the nail and locking screws. They include drill bit kits, hand and flexible reamers, an awl, trocars, guide wires, a bone depth gauge, a slap hammer impactor/extractor, an X-ray overlay, a metal ruler, a screw extractor, sterilization boxes, guides, wrenches and other tools.

6. **Intended Use**

The Orthofix Femoral Nailing System is indicated for the following: traumatic fractures; pathological fractures; refractures; non-unions; reconstructive surgery; and bone transport.

7. **Substantial Equivalence**

The information provided in this submission demonstrates that the Orthofix Femoral Nailing System is substantially equivalent to legally marketed predicate femoral nailing systems. First, most of the components and instrumentation in this system are either identical to or comparable to those in our Tibial Nailing System (K961027). Secondly, these components and instrumentation are substantially equivalent to those provided in the predicate systems. Two such predicate devices are the Howmedica Grosse & Kempf

Locking Nail System (K860756) and Smith & Nephew Richards Femoral Interlocking Nail System. The Orthofix Femoral Nailing System and the legally marketed predicate devices are substantially equivalent in intended use, indicated use, material composition, size and shape.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

Mr. Robert L. Sheridan
Vice President, Device Evaluation
C.L. McIntosh & Associates, Inc.
Representing Orthofix Srl
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K973944
Orthofix® Femoral Nailing System
Regulatory Class: II
Product Code: HSB
Dated: October 14, 1997
Received: October 16, 1997

Dear Mr. Sheridan:

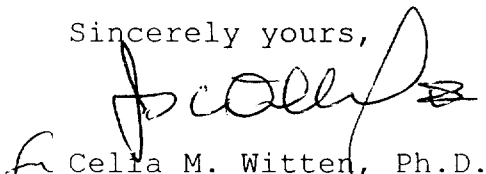
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

Device Name: Orthofix Femoral Nailing System

Indications For Use: The Orthofix Femoral Nailing System is indicated for the following: traumatic fractures; pathological fractures; refractures; non-unions; reconstructive surgery; and bone transport.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: + OR Over-The-Counter: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973944