MAR 18 1998

K974186

510(k) SUMMARY[1]
Orthofix® External Fixation Screw
March 3, 1998

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

2.1 Trade/Proprietary Name

Orthofix® External Fixation Screw (Pin) With Hydroxyapatite Coating

2.2 Common/Usual Name

External fixation pin

2.3 Classification Name

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

3. Applicant/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

4. Reason for Submitting the 510(k)

Orthofix intends to commercially distribute a modified version of its previously 510(k)-cleared external fixation pin. Orthofix wishes to distribute its pins with a very thin plasma sprayed coating of hydroxyapatite (HA).

5. Device Description

The Orthofix Hydroxyapatite Coated Screws are manufactured from surgical grade stainless steel AISI 316L. The pins are available in a variety of diameters and lengths. The threaded end is gradually tapered, over approximately the last third of the pin's length. The threaded portion of the pin is coated with a very thin plasma sprayed coating of HA. The HA powder used in the plasma spray coating process conforms to ASTM F 1185. The mechanical properties of the coating conform to ASTM F 1501.

6. Indications For Use

The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

7. Substantial Equivalence

The decision that the Orthofix HA coated pin is substantially equivalent to a legally marketed predicate device is reached through consideration of the requirements for substantial equivalence determinations. These requirements are set forth in the document entitled "Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program", which was published on June 30, 1986 by the Center for Devices and Radiological Health (CDRH),

FDA guidance documents relevant to this application were used in its preparation. In particular, the guidance document, "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" (revised February 20,1997), was followed in the preparation of this 510(k). The physical, mechanical and chemical tests prescribed by FDA in its guidance document to characterize the HA coating and HA/substrate interface were conducted.

The substantial equivalence of the Orthofix HA coated pins is supported by the extensive laboratory, animal and clinical testing data presented herein. The preclinical and clinical data presented herein demonstrate that the use of the proprietary HA-coating enhances fixation at the pin/bone interface. The Orthofix HA-coated pins demonstrate statistically significantly better stability or fixation at the time of removal or extraction than do the uncoated pins.

Orthofix pins with the proprietary HA-coating were found in randomized controlled clinical and animal studies to have significantly enhanced fixation and a reduced incidenced of clinical loosening. The clinical results demonstrate:

- No significant difference in the insertion torques for standard uncoated and HA-coated Orthofix pins in both metaphyseal and diaphyseal bone.
- The extraction torque is significantly greater for HA-coated Orthofix pins than for uncoated pins in both metaphyseal and diaphyseal bone.

- For the HA-coated Orthofix pins, the extraction torque is significantly greater than the insertion torque in both metaphyseal and diaphyseal bone; whereas, for the uncoated pins, the extraction torque is significantly lower than the insertion torque in both metaphyseal and diaphyseal bone.

The animal study that was conducted compared uncoated and HA-coated Orthofix pins. Radiographic, histologic, SEM and histomorphometric analyses demonstrate that osseointegration with direct contact between the bone and the screw threads of the Orthofix HA-coated pins.

As reported in the literature, complications of external fixation include pin tract infection and loosening. The enhanced fixation and improved stability at the bone-pin interface seen with the Orthofix Ha-coated pins significantly reduces the incidence of pin loosening. It is generally accepted that a loose pin provides an increased risk of infection.

In summary, the information and data provided in this submission are consistent with FDA's guidance documents for HA coated orthopedic implants and demonstrate that the Orthofix HA coated pin is substantially equivalent to legally marketed predicate devices.

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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))

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 1998

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

Re: K974186
Trade Name: Orthofix® External Fixation Screw (Pin) with Hydroxyapatite Coating
Regulatory Class: II
Product Code: JDW
Dated: March 3, 1998
Received: March 4, 1998

Dear Mr. Sheridan:

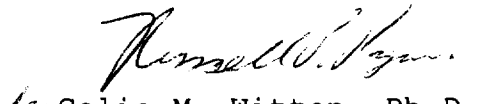
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



for 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 External Fixation Screw (Pin) With Hydroxyapatite Coating

Indications For Use: The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices

11/5/9711:11 510(k) Number K974186