K070555

JUL 13 2007

510(k) Summary

July 12th, 2007

This safety and effectiveness summary for the OrthoPro Steinman Pins and Kirschner Wires is provided as required per section 513(i)(3) of the Food, Drug, and Cosmetic Act.

510(k) Owner:

OrthoPro LLC.
3450 S. Highland Dr. #303
Salt Lake City, UT 84106
Telephone: 801-746-0208

Authorized Contact Person:
Christopher L. Cook
Straits Orthopaedics Inc.
13115 NE 4th St. Suite 130
Vancouver, WA 98684
Telephone: 360-253-9761

Trade Name: OrthoPro Steinman Pins and Kirschner Wires

Common Name: Steinman Pins
Kirschner Wires

Classification Name: Smooth or threaded metallic bone fixation fastener

Classification: 888.3040

Product Class: II

Product Code: HTY pin, fixation, smooth
JDW pin, fixation, threaded

Predicate or legally marketed devices which are substantially equivalent:

Product	510k Number
DePuy Steinman Pins and Kirshner Wires	K960385
Smith and Nephew Pins and Wires	K994143
Smith and Nephew Pins and Wires	Pre-amendment

Device Description
The OrthoPro Steinman Pins and Kirschner Wires are offered in a variety of lengths, diameters, tip styles, and threading. These devices are constructed of implant grade 316LVM stainless steel conformant to ASTM F138, are provided non-sterile, and are intended for single-use only

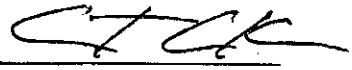
Intended Use
The OrthoPro Steinman Pins and Kirschner Wires are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Comparison of the technological characteristics of the device to predicate and legally marketed devices
The proposed devices are substantially equivalent to the identified predicate device in materials of construction, physical characteristics, and intended use.

Summary of Non-Clinical Tests
The non-clinical testing to be conducted on the OrthoPro Steinman Pins and Kirschner Wires will include material and dimensional verification.

The OrthoPro Steinman Pins and Kirschner Wires are equivalent in physical dimensions and materials to the identified predicate devices. Testing, therefore, is not needed to demonstrate that the subject devices are substantially equivalent to the legally marketed predicate devices.

Contact:



Christopher L. Cook
Authorized Contact Person
Vice President Regulatory Affairs
Straits Orthopaedics Inc.

2.7 Classification: 888.3040

2.8 Panel Orthopedic

2.9 Product Class: II

2.1.0 Product Code HTY pin, fixation, smooth
JDW pin, fixation, threaded

2.1.1 Predicate Devices

Product	510k Number
DePuy Steinman Pins and Kirschner Wires	K960385
Smith and Nephew Pins and Wires	K994143
Smith and Nephew Pins and Wires	Pre-amendment

3.0 Device Description

The OrthoPro Pins and Wires product family is available in a range of lengths, diameters, and tip styles, with and without threading.

3.1 Materials of Construction
All pins and wires are manufactured from 316LVM surgical implant grade stainless steel certified to ASTM F138.

3.2 Diameter
The devices will range in diameter from 0.028 inches to 0.1875 inches.

3.2 Length
The devices range in length from 4 inches to 12 inches.

3.3 Distal Tip Style
The devices are available in a variety of tip styles, including but not limited to trocar point, diamond point, and cove point.

3.4 Proximal Tip Style
The devices will have proximal tip styles including but not limited to trocar point, diamond point, check point, and round.

3.5 Threading
The devices will be provided in fully threaded, partially threaded and non-threaded versions.

3.6 Device Specifications
Please refer to Appendix B for detailed device specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

OrthoPro LLC
c/o Straits Orthopaedics Inc.
Mr. Christopher L. Cook
Vice President Regulatory Affairs
13115 NE 4th Street, Suite 130
Vancouver, WA 98684

Re: K070555
Trade/Device Name: OrthoPro Steinman Pins and Kirschner Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JDW, HTY
Dated: June 1, 2007
Received: June 11, 2007

Dear Mr. Cook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

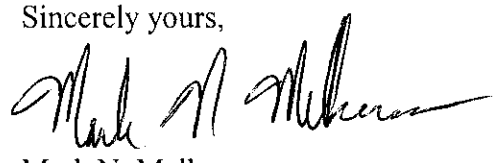
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If Known) K070555

Device Name: OrthoPro Steinman Pins and Kirschner Wires

Indications for Use:

OrthoPro Steinman Pins and Kirschner Wires
Indications for Use

The OrthoPro Steinman Pins and Kirschner Wires are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Prescription Use X
(Part 21 CFR 801 Subpart D

Over the Counter Use
(21 CFR 807 Subpart C)

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

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070555