K102215
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5. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	Evergreen Orthopedics Research Lab d/b/a Operativ 11321 NE 120th St. Kirkland, WA 98034
510(k) CONTACT:	Wayne Morse, CCE, FACCE wayne.morse@operativ.com
DATE PREPARED:	July 15, 2010, Revised October 8, 2010
TRADE NAME:	Kirschner wires and Steinmann Pins
COMMON NAME:	Internal/external bone fixation devices
CLASSIFICATION:	888.3040 smooth or threaded bone fixation fasteners
DEVICE PRODUCT CODE:	HTY pin, fixation, smooth JDW pin, fixation, threaded
PRODUCT CLASS:	II
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Kirschner wires and Steinmann pins (K960385), Smith and Nephew (K994143), Orthopro (K070555), and Telflex (K030336)
DEVICE DESCRIPTION:	The Operativ internal/external fixation devices consist of various fixation pins and wires for in unilateral internal/external fixation. The various lengths, sizes and end configurations are offered to accommodate various patient anatomies, injuries and/or conditions, and physician preference. Calibrated wires provide etched markings every ½ inch. All Operativ internal/external fixation devices included in this submission are manufactured from stainless steel and will be offered non-sterile.
INTENDED USE:	The Kirschner wires and Steinmann pins are indicated for use in fixation of bone

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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.

SUBSTANTIAL EQUIVALENCE:

The device is similar in intended use, materials, design, and performance characteristics to the DePuy K-wires, Steinmann pins. The determination of substantial equivalence for this device was based on a detailed description and conformance with voluntary standards.

SUMMARY OF TESTING:

Based upon the similarities in materials and design to the predicate devices, the technological characteristics are sufficient to support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Evergreen Orthopedics Research Lab
% Operativ
Mr. Wayne Morse, CCE, FACCE
11321 Northeast 120th Street
Kirkland, Washington 98034

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Re: K102215
Trade/Device Name: Operativ 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: HTY, JDW
Dated: October 8, 2010
Received: October 12, 2010

Dear Mr. Morse:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

4. INDICATIONS FOR USE:

510(k) Number (if known) K102215

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Device Name: Operativ Steinman pins and Kirschner Wires

Indications for Use:

Operativ Steinman pins and Kirschner wires indication for use

The Operativ Kirschner wires and Steinmann pins 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 _____
(Part 21 CFR 801 subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K10 2215