

510(K) Summary – K111086

JUN 17 2011

SUMMARY OF SAFETY AND EFFECTIVENESS

April 15, 2011 – Revised June 7, 2011

NAME OF FIRM: OrthoPediatrics, Corp.
2850 Frontier Drive
Warsaw, Indiana 46582
Establishment Registration No.:3006460162

510(K) CONTACT: Mark Fox
Vice President of Regulatory Affairs
Tel: (574) 268-6379
Fax: (574) 269-3692

TRADE NAME: OrthoPediatrics Fracture and Osteotomy
Bone Plate System

COMMON NAME: Bone Plates and Bone Screws

**RECOMMENDED
CLASSIFICATION:**

21 CFR 888.3030: Single/Multiple components metallic bone fixation
appliances and accessories: Class II per 21 CFR §888.3030

21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener:
Class II per 21 CFR §888.3040

Recommended Class: II

DEVICE PRODUCT CODE(S): HRS, (Plate, Fixation, Bone)
HWC, (Screw, Fixation, Bone)

DEVICE DESCRIPTION:

The OrthoPediatrics Fracture and Osteotomy Bone Plate System will combine implants and instruments in one convenient system. This system will offer the advantages of the osteotomy blade plates and cannulated instrumentation. Osteotomy plates provide ease of reduction and good rotational stability while maintaining bone stock. Cannulated instruments work over a guide wire for precise placement and safety.

INDICATIONS FOR USE:

The **OrthoPediatrics** Fracture and Osteotomy Bone Plate System is intended for temporary internal fixation and stabilization of long bone fractures and osteotomies, mal-unions and non-unions, in pediatric and small stature adults. Specific indications include: intertrochanteric derotation and varus osteotomies, femoral neck and pertrochanteric fractures, intertrochanteric valgus osteotomies.

PREDICATE DEVICES:

K062872, Pediatric LCP Hip Plate System, Synthes (USA)

K072095, Pediatric LCP Hip Plate System Modifications, Synthes (USA)

K083286, PediLoc Locking Plate System, Orthopediatrics

K082949, OrthoPediatrics Bone Screws, OrthoPediatrics

K100240, PediLoc Tibial Plate System, OrthoPediatrics

K070906, Periarticular Locking Plate System, Zimmer

K003496, Cannulated Screw System, Pioneer

MATERIALS:

All implant components are manufactured from medical grade metals including 316L stainless steel which meets the ASTM-F138 standard. In addition, the cannulated screws are manufactured from medical grade BIODUR stainless steel which meets ASTM 2229-07 standard.

TECHNOLOGIC CHARACTERISTICS:

The fundamental scientific principles and technological characteristics, including the intended use, material, sizes, and general design are the same as, or similar to, the predicate devices.

Summary of technological characteristics:

1. Plate thickness(s) and width(s) are substantially equivalent to predicates.
2. Identical materials to cited predicates.
3. Range of plate angles are substantially equivalent to predicates.
4. Range of screw sizes and threads are substantially equivalent to predicates.
5. Indications for Use is substantially equivalent to predicates.

The technological characteristics of the subject device and the predicates are substantially equivalent to the predicates.

PERFORMANCE ANALYSIS:

Subject device has similar configuration, sizes and design as the predicate device(s). Engineering calculations with worst case loading calculations of subject device and corresponding predicate device, confirmed that subject device has equivalent or better strength and resistance to bending moments. A review of the MAUDE complaint data base of similar predicate devices support the safety and effectiveness of the device.

FUNCTION:

The system functions to provide immediate stability and temporary fixation during the natural healing process.

EQUIVALENCY:

Therefore, since materials, intended use, and technological features used in the **OrthoPediatrics** Fracture and Osteotomy Bone Plate System are similar to the predicate devices, safety and efficacy is expected to be equivalent.



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

OrthoPediatics, Corporation
% Mr. Mark Fox
Vice President of Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46582

JUN 17 2011

Re: K111086

Trade/Device Name: OrthoPediatics Fracture and Osteotomy Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: April 15, 2011
Received: April 19, 2011

Dear Mr. Fox:

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 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.

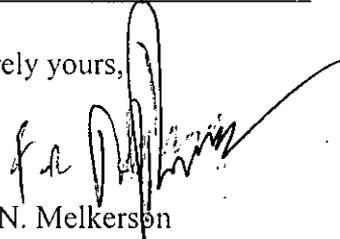
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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. Melkersen
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K111086

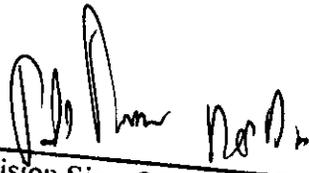
Device Name: OrthoPediatrics Fracture and Osteotomy Bone Plate System

The **OrthoPediatrics Fracture and Osteotomy Bone Plate System** is intended for temporary internal fixation and stabilization of long bone fractures and osteotomies, mal-unions and non-unions, in pediatric and small stature adults. Specific indications include: intertrochanteric derotation and varus osteotomies, femoral neck and pertrochanteric fractures, intertrochanteric valgus osteotomies.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K111086