K083286 (pg. 1 of 2) JAN 30 2009

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:
OrthoPediatrics, Corp.
210 N. Buffalo Street
Warsaw, Indiana 46580
Establishment Registration No.: 9102640

510(K) CONTACT:
Gary Barnett
VP-Regulatory & Medical Affairs
Tel: (574) 268-6379
Fax: (574) 269-3692

TRADE NAME: OrthoPediatrics PediLoc ™ Locking Plate System

COMMON NAME: Bone Plates and Bone Screws

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

DEVICE PRODUCT CODE(S): HRS and HWC

SUBSTANTIALLY EQUIVALENT DEVICES:

S&N Locking Bone Plate System (K033669), Smith & Nephew
S&N Peri-Loc Locking Bone Plate System (K051735), Smith & Nephew
Pedi-Plate Bone Plate System (K073344, K081407), OrthoPediatrics, Corp.
Synthes Locking Compression Plate System (K062564), Synthes (USA)

DEVICE DESCRIPTION:

A pediatric small fragment set offers advantages of both conventional and locking plate fixation devices and instrumentation in one system. Utilizing both locking and non-locking screws Pedi-Loc will offer a construct that resists angular collapse while simultaneously acting as an effective aid to fracture reduction.

The OrthoPediatrics PediLoc™ Locking Plate System is used for pediatric patients as indicated for pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle. Indications for buttressing multi-fragmentary distal femoral fractures include: supracondylar, intra-articular and

extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, non-unions and mal-unions, and osteotomies of the femur.

- Materials: The devices are manufactured from 316L stainless steel which meets the ASTM-F138 standard.
- Function: The system functions to provide immediate stability and temporary fixation during the natural healing process.

INDICATIONS FOR USE:

The OrthoPediatrics PediLoc™ Locking Plate System is used for pediatric patients as indicated for pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle. Indications for buttressing multi-fragmentary distal femoral fractures include: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, non-unions and mal-unions, and osteotomies of the femur.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

OrthoPediatrics believes that this system is substantially equivalent to the legally marketed predicate devices based on similarities in design, materials, and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2009

OrthoPediatrics Corp.
C/o Mr. Gary D. Barnett
V.P. Regulatory & Medical Affairs
210 North Buffalo Street
Warsaw, Indiana 46580

Re: K083286
Trade/Device Name: OrthoPediatrics PediLoc™ Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 5, 2008
Received: November 5, 2008

Dear Mr. Barnett:

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.

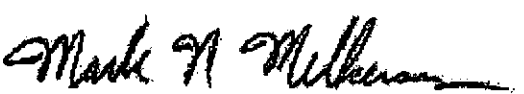
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K083286

Device Name: OrthoPediatrics PediLoc ™ Locking Plate System

The OrthoPediatrics PediLoc™ Locking Plate System is used for pediatric patients as indicated for pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle. Indications for buttressing multi-fragmentary distal femoral fractures include: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, non-unions and mal-unions, and osteotomies of the femur.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 General, Restorative, and Neurological Devices

510(k) Number K083286