JUL 22 2008

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, Engineering & Operations
Tel: (574) 268-6379
Fax: (574) 269-3692

TRADE NAME: OrthoPediatrics PediPlates ™ System

COMMON NAME: Plate, Fixation, Bone

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

DEVICE PRODUCT CODE(S): HRS and HWC

SUBSTANTIALLY EQUIVALENT DEVICES:

- Guided Growth Plate (K031493), Marketed by Orthofix
- TC-100 Plating and Screw System (K993106), Smith & Nephew
- PediPlate ™ Plating System (K073344), OrthoPediatrics
- Distal Tibia T-Plates (K080522), Synthes

DEVICE DESCRIPTION:

The two and four-hole plates feature a contoured mid-section and low profile for pediatric use. There is an alignment mark in the center of the O and I-Plates to aid accurate placement of the device relative to the growth plate that is localized radiographically. The plates are available in various sizes to accommodate variations in bone size and geometry. The plate is transfixed to bone using two to four screws, depending on which plate is selected.

- Materials: The devices are manufactured from 316L stainless steel, which meet ASTM F138 or ASTM F139.
- Function: The system functions to provide immediate stability and temporary fixation during the natural healing process.

The OrthoPediatrics PediPlate ™ System is intended for use in the treatment of pelvic, small and long bone fractures, as well as deformity corrections of pediatric patients' long

bones, which includes osteotomies and redirecting the angle of growth of children's long bones. The system includes cortical and cannulated screws, and specialty plates, referred to as O, I, and H-Plates.

INDICATIONS FOR USE:

The OrthoPediatrics PediPlate system is used for adult and pediatric patients as indicated for pelvic, small and long bone fractures. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerous, ulna, middle hand and middle foot bones, treatment of the calcaneal; hip arthodesis, and provisional hole fixation; as well as for redirecting the angle of growth of long bones. This is useful for gradually correcting angular deformities in growing children.

Specific pediatric conditions/diseases for which the devices will be indicated include:

- Valgus, varus, or flexion, extension deformities of the knee (femur and/or tibia)
- Valgus, varus, or plantar flexion deformities of the ankle
- Valgus or varus deformities of the elbow (humerus)
- Radial or ulnar deviation, flexion or extension deformities of the wrist (radius)

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

FEB 19 2009

OrthoPediatrics, Corporation
% Mr. Gary Barnett
Vice President, Regulatory, Engineering & Operations
210 N. Buffalo Street
Warsaw, Indiana 46580

Re: K081407
Trade/Device Name: OrthoPediatrics PediPlates™ 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, OBT
Dated: May 14, 2008
Received: May 19, 2008

Dear Mr. Barnett:

This letter corrects our substantially equivalent letter of July 22, 2008.

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 (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.

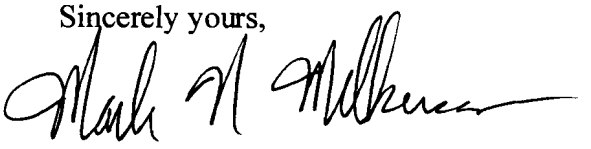
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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 continue 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.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): K081407

Device Name: OrthoPediatrics Plating System

The OrthoPediatrics PediPlate system is used for adult and pediatric patients as indicated for pelvic, small and long bone fractures. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerous, ulna, middle hand and middle foot bones, treatment of the calcaneal; hip arthodesis, and provisional hole fixation; as well as for redirecting the angle of growth of long bones. This is useful for gradually correcting angular deformities in growing children.

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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)

Mark N Milhous

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

510(k) Number K081407