K100240 (pg 1/2)

MAY 17 2010

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™ Tibial 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

PRODUCT CODE:
HRS, HWC

SUBSTANTIALLY EQUIVALENT DEVICES:

K080522, LCP Distal Tibia T-Plates, Synthes
K083286, PediLoc Locking Plate System, OrthoPediatrics
K090666, PediPlate System, OrthoPediatrics

DEVICE DESCRIPTION:

The **OrthoPediatrics** PediLoc™ Tibial Plates are machined metallic plates that offer screw to plate locking designed for various fracture modes of the distal end of the tibia and other small bones.

- Intended use: OrthoPediatrics PediLoc™ Tibial Plates are indicated for fractures, osteotomies, and non-unions of the pediatric and small stature adult tibia.
- 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.

- Technological Characteristics: Components comprising OrthoPediatrics PediLocTM Tibial Plate (and screws) System are similar to the predicate devices listed above in that they share indications for use, are made from similar materials, and incorporate similar technological characteristics.
- Performance Characteristics: Engineering (strength) calculations were included demonstrating these devices are as strong as the devices cleared through K080522.

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

OrthoPediatrics Corp.
% Gary D. Barnett
210 N. Buffalo Street
Warsaw, Indiana 46580

MAY 1 7 2010

Re: K100240
Trade/Device Name: OrthoPediatrics PediLoc Tibia Plate System
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 4, 2010
Received: May 11, 2010

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. 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

Indications for Use Statement

510(k) Number (if known): K100240 (pg 1/1)

Device Name: OrthoPediatrics PediLoc™ Tibial Plate System

OrthoPediatrics PediLoc™ Tibia Plates are indicated for fractures, osteotomies, and non-unions of the pediatric and small stature adult tibia.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100240