JUL 2 9 2014

510(k) Summary

NAME OF FIRM:	OrthoPediatrics, Corp. 2850 Frontier Drive Warsaw, IN 46582
DATE PREPARED:	June 16, 2014
510(K) CONTACT:	Mark Fox Vice President, Regulatory Affairs Tel: (574) 268-6379
PROPOSED TRADE NAME:	PediLoc Fragment System
DEVICE CLASSIFICATION:	Class II; 21 CFR 888.3030 and 21 CFR 888.3040
CLASSIFICATION NAME:	Single/multiple component metallic bone fixation appliances and accessories. Smooth or threaded metallic bone fixation fastener.
PRODUCT CODE:	KTT, HRS, HWC, HTN
DEVICE DESCRIPTION:	The OrthoPediatrics' PediLoc Fragment System combines implants and instruments in one convenient and comprehensive system. This System provides immediate stability and temporary fixation of bones during the healing process with conventional plating technology and fixation techniques.
INDICATIONS FOR USE:	OrthoPediatrics' PediLoc Fragment System is intended to provide temporary internal fixation and stabilization of long bones, short (small) bones, pelvis, and scapula. This includes fractures, osteotomies, mal-unions, and non-unions in all pediatric subgroups (except neonates), and small stature adults.
MATERIALS:	Medical grade Stainless Steel Medical grade cobalt-chromium-molybdenum
PREDICATE DEVICES:	OrthoPediatrics Fracture and Osteotomy Bone Plate System (K111086) OrthoPediatrics PediLoc Locking Plate System (K083286) OrthoPediatrics Bone Screws (K082949) Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684)

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

PERFORMANCE DATA: Tests performed according to ASTM Standards, demonstrated that the device performs as well as or better than the predicate devices.

NONCLINICAL TESTING: Nonclinical testing included mechanical laboratory (bench) testing. Static and dynamic testing in addition to FEA analysis and comparisons of the subject devices with legally marketed predicates identified within this submission were performed. Dimensional comparison review and analysis with engineering rational provided additional nonclinical supportive data. The subject devices performed as well as or better than the predicate devices.

CONCLUSION: The OrthoPediatrics' PediLoc Fragment System has the same intended use and technological characteristics as the predicate devices. Therefore the OrthoPediatrics' PediLoc Fragment System is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 29, 2014

OrthoPediatrics Corporation
Mr. Mark Fox
V. P. Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K140431
Trade/Device Name: PediLoc Fragment 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, HTN, KTT
Dated: June 16, 2014
Received: June 17, 2014

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. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K140431

Device Name: **OrthoPediatrics' PediLoc Fragment System**

Indications for Use:

OrthoPediatrics' PediLoc Fragment System is intended to provide temporary internal fixation and stabilization of long bones, short (small) bones, pelvis, and scapula. This includes fractures, osteotomies, mal-unions, and non-unions in all pediatric subgroups (except neonates), and small stature adults.

Prescription Use ___X___ or Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140431