K083726 #1/2

MAR 11 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 PediNail ™ Intramedullary Nailing System

COMMON NAME:

Intramedullary nail

CLASSIFICATION:

21 CFR 888.3020: Intramedullary fixation rod and accessories: Class II per 21 CFR §888.3020

DEVICE PRODUCT CODE(S): HSB

SUBSTANTIALLY EQUIVALENT DEVICES:

K040929, Tri-Gen Adolescent TAN, Smith & Nephew
K070843, Adolescent Lateral Entry Nail, Synthes
K983942, Intramedullary Nail System (stainless steel), Smith & Nephew
K993956, Titanium Pediatric Femoral Nail, Biomet
K072161, Femoral Locking Nail System, Biomet
K040336, Lateral Entry Femoral Nail System, Synthes

DEVICE DESCRIPTION:

OrthoPediatrics intramedullary rods (nails) are generally rod-shaped devices, with screw holes at either end for fixation to bone. This device is intended to be inserted into the medullary canal of the femur for fixation of fractures by aligning and stabilizing the bone fragments. Additional stabilization may be realized by installing transverse screws through holes in the rod. These devices are made of medical grade stainless steel.

The OrthoPediatrics PediNail™ system is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of

K083726 #2/2

impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity.

Additional indications include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; polytrauma and multiple fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; fixation of fractures that occur in and between the proximal and distal third of the long bones being treated. The OrthoPediatrics' PediNail™ is for single use only.

- 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 PediNail™ system is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity.

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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.

Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2009

Orthopediatrics, Corp.
% Mr. Gary Barnett
VP, Regulatory & Medical Affairs
210 North Buffalo Street
Warsaw, Indiana 46580

Re: K083726
Trade/Device Name: OrthoPediatrics PediNail™ Intramedullary Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: December 10, 2008
Received: December 15, 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 Biometric's (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): K083726

Device Name: OrthoPediatrics PediNail ™ Intramedullary Nailing System

The OrthoPediatrics PediNail™ system is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity.

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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)

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

510(k) Number _____