

K083726 #1/2

MAR 11 2009

## **SUMMARY OF SAFETY AND EFFECTIVENESS**

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**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

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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 OrthoPediatics' 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 OrthoPediatics 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:**

OrthoPediatics 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.



MAR 11 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K083726

Trade/Device Name: OrthoPediatics 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.

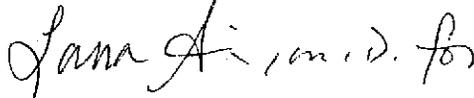
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Gary Barnett

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: OrthoPediatics PediNail™ Intramedullary Nailing System**

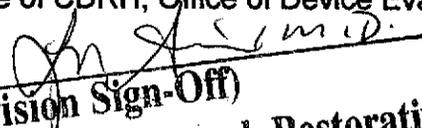
The OrthoPediatics PediNail™ system is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of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

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Prescription Use  X  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (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 \_\_\_\_\_

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