DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 23, 2014

NEOORTHO Produtos Ortopédicos S/A
% Mr. Kevin A. Thomas, PhD
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K141103
Trade/Device Name: Intramedullary Nail and Screws - NEONAIL
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 28, 2014
Received: August 28, 2014

Dear Dr. Thomas:

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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141103

Device Name

Intramedullary Nail and Screws – NEONAIL

Indications for Use *(Describe)*

Intramedullary Nail and Screws for Femur – NEONAIL is indicated for femoral fracture fixation including:
• Open and closed femoral fractures;
• Pseudoarthrosis and correction osteotomy;
• Pathologic fractures, impending pathologic fractures, and tumor resections;
• Ipsilateral femur fractures;
• Fractures distal to the hip joint; and
• Nonunions and malunions.

Intramedullary Nail and Screws for Tibia – NEONAIL is intended to provide temporary stabilization of various types of fractures, malunions or nonunions of the tibia. Intramedullary Nail and Screws for Tibia – NEONAIL is indicated for tibial fracture fixation, which may include:
• Open and closed tibial fractures;
• Pseudoarthodlosis and correction osteotomy;
• Pathologic fractures, impending pathologic fractures and tumor resections; and
• Nonunions and malunions.

The Intramedullary Nail and Screws for Humerus – NEONAIL is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include nonunions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications include: AO classification Type A fractures, dislocated; AO classification Type B fractures, dislocated; AO classification Type C fractures with intact calotte; and humeral fractures according to the Neer Classification.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
NEOORTHO Produtos Ortopédicos S/A
Intramedullary Nail and Screws – NEONAIL
K141103

September 18, 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name	NEOORTHO Produtos Ortopédicos S/A Rua Ângelo Domingos Durigan, 607, Cascatinha Curitiba, Paraná 82025-100, Brazil Telephone: +55 41 3535-1000 Fax: +55 41 3535-1018
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Intramedullary Nail and Screws - NEONAIL
Common Name	Rod, fixation, intramedullary and accessories
Classification Name	Intramedullary fixation rod
Classification Regulations	21 CFR 888.3020, Class II
Product Code	HSB
Classification Panel	Orthopedic Products Panel
Reviewing Branch	Joint Fixation Branch One

INTENDED USE

Device Name: Intramedullary Nail and Screws – NEONAIL
Femur

Intramedullary Nail and Screws for Femur – NEONAIL is indicated for femoral fracture fixation including:

- Open and closed femoral fractures;
- Pseudoarthrosis and correction osteotomy;
- Pathologic fractures, impending pathologic fractures, and tumor resections;
- Ipsilateral femur fractures;
- Fractures distal to the hip joint; and
- Nonunions and malunions.

Device Name: Intramedullary Nail and Screws – NEONAIL
Tibia

Intramedullary Nail and Screws for Tibia – NEONAIL is intended to provide temporary stabilization of various types of fractures, malunions or nonunions of the tibia. Intramedullary Nail and Screws for Tibia – NEONAIL is indicated for tibial fracture fixation, which may include:

- Open and closed tibial fractures;
- Pseudoarthodlosis and correction osteotomy;
- Pathologic fractures, impending pathologic fractures and tumor resections; and
- Nonunions and malunions.

Device Name: Intramedullary Nail and Screws – NEONAIL
Humerus

The Intramedullary Nail and Screws for Humerus – NEONAIL is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include nonunions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications include: AO classification Type A fractures, dislocated; AO classification Type B fractures, dislocated; AO classification Type C fractures with intact calotte; and humeral fractures according to the Neer Classification.

DEVICE DESCRIPTION

An intramedullary nail is a metal rod implanted into the medullary cavity of a bone to treat fractures that occur in long bones of the body. Intramedullary Nail and Screws – NEONAIL consists of metal rods, bone screws, and end caps. All components are made from Ti-6Al-4V alloy. The rods are cannulated and are provided with screw holes to accommodate screws of various diameters and lengths. The rods are available in a range of sizes used for specific anatomic locations and fracture configurations.

EQUIVALENCE TO MARKETED DEVICE

Intramedullary Nail and Screws – NEONAIL is substantially equivalent in indications and design principles to the following predicate devices:

- Howmedica Osteonics Corp., T2 Femoral Nail, K010801
- Stryker, T2 Femoral Nail Model 1825-XXXXCP, 1828-XXXXCP, K112059
- Stryker Trauma AG, T2 Tibial Nailing System, K131365
- Howmedica Osteonics Corp., T2 Proximal Humeral Nail, K042396
- Howmedica Osteonics Corp., T2 Nailing System, K032523

Intramedullary Nail and Screws – NEONAIL components have similar designs and identical materials as those cleared under K010801, K112059, K131365, K042396, and K032523. Intramedullary Nail and Screws for Femur – NEONAIL is similar in indications, design, and dimensions to those cleared in K010801 and K112059. Intramedullary Nail and Screws for Tibia – NEONAIL is similar in indications, design, and dimensions to those cleared in K131365. Intramedullary Nail and Screws for Humerus – NEONAIL is similar in indications, design, and dimensions to those cleared in K042396 and K032523.

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: engineering analysis, dimensional analysis and mechanical testing. The worst case nail for each indication in the Intramedullary Nail and Screws – NEONAIL product list was subjected to mechanical performance testing according to ASTM F1264 *Standard Specification and Test Methods for Intramedullary Fixation Devices* (static four-point bending, static torsion, and bending fatigue).

The worst case screws available in the Intramedullary Nail and Screws – NEONAIL product list were subjected to mechanical performance testing according to ASTM F1264 *Standard Specification and Test Methods for Intramedullary Fixation Devices* (static four-point bending and bending fatigue) and ASTM F543 *Standard Specification and Test Method for Metallic Bone Screws* (torsional properties, driving torque, axial pullout strength, and self-tapping performance).

Clinical data were not submitted in this premarket notification.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, Intramedullary Nail and Screws – NEONAIL has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has similar packaging.