DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Neoortho Productos Orthopedicos S/A
% Mr. Kevin Thomas
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

December 16, 2014

Re: K142419
Trade/Device Name: Mini and Micro Fragments Reconstruction System-Neofix
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
Dated: October 15, 2014
Received: October 16, 2014

Dear Mr. 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" (21 CFR 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,

Mark N. Melkerson -S

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)*
K142419

Device Name

Mini and Micro Fragments Reconstruction System – NEOFIX

Indications for Use *(Describe)*

Mini and Micro Fragments Reconstruction System – NEOFIX is intended for small bone fracture fixation, arthrodesis, reconstruction, and osteotomy fixation. Examples include small bones of the hand, wrist, foot and ankle. The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
NEOORTHO Produtos Ortopédicos S/A
Mini and Micro Fragments Reconstruction System – NEOFIX
K142419

December 8, 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	Mini and Micro Fragments Reconstruction System – NEOFIX
Common Name	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification Regulations	21 CFR 888.3030, 21 CFR 888.3040, Class II
Product Code	HRS, HWC
Classification Panel	Orthopedic Products Panel
Reviewing Branch	Joint Fixation Devices Branch Two (JFDB2)

INTENDED USE

Mini and Micro Fragments Reconstruction System – NEOFIX is intended for small bone fracture fixation, arthrodesis, reconstruction, and osteotomy fixation. Examples include small bones of the hand, wrist, foot and ankle. The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone.

DEVICE DESCRIPTION

Mini and Micro Fragments Reconstruction System – NEOFIX consists of plates and screws in a variety of designs and sizes. Straight plates are provided in various lengths and may be contoured to adapt to patient specific anatomy. Straight plates are available with screw holes to accommodate non-locking and locking screw designs. Plates also are provided in various geometric configurations that are commonly used in trauma and reconstructive surgery. The plates range in thickness from 0.7 mm to 2.7 mm, and are manufactured from commercially pure titanium conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications* or Ti-6Al-4V ELI alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.*

Self-tapping cortical screws are provided in locking and non-locking designs. The locking screws are provided with a thread diameter of 2.4 mm with a hexalobular instrument interface (Star Head) and a tapered thread tip to facilitate insertion. Locking smooth pins also are provided with a diameter of 2.4 mm in various lengths. The smooth pins are used with the Distal Radius Volar Plates. Non-locking cortical self-tapping screws are provided with thread diameters of 1.5, 2.0, 2.3, 2.4 and 2.7 mm, and in various lengths from 5 mm to 32 mm. The non-locking screws with thread diameters of 1.5, 2.0 and 2.3 mm have a cruciform instrument interface; the non-locking screws with diameters of 2.4 and 2.7 mm have a hexalobular instrument interface. All screws are manufactured from Ti-6Al-4V ELI alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.*

EQUIVALENCE TO MARKETED DEVICE

NEOORTHO Produtos Ortopédicos S/A submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K090047, Synthes (USA), Synthes (USA) 1.5 mm Mini Fragment LCP System

K063049, Synthes (USA), Synthes (USA) Modular Mini Fragment LCP System

K102694, Synthes (USA), Synthes (USA) 2.4 mm Variable Angle LCP Dorsal Distal Radius Plates

K071184, Synthes (USA), Synthes Variable Angle-locking Compression Plate (VA-LCP) Distal Radius System

K083694, Synthes (USA), Synthes 2.4 mm VA-LCP Two-Column Volar Distal Radius Plates

K091644, Synthes (USA), Synthes (USA) 2.4 mm LCP Volar Column Distal Radius Plates

K092556, Synthes (USA) 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius Plates

K012114, Synthes (USA), Synthes Locking Distal Radius Plating System

K102641, NEOORTHO Produtos Ortopédicos S/A, Mini and Micro Fragments Reconstruction System – NEOFACE

K982732, Synthes (USA), Synthes (USA) Distal Radius Plate System

K113733, NEOORTHO Produtos Ortopédicos S/A, Small and Large Fragments Osteosynthesis System NEOFIX

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials. The subject and predicate devices encompass the same range of physical dimensions, and share similar characteristics including locking and non-locking plate and screw designs. The subject and predicate devices are packaged using the same materials, and are to be sterilized by the same methods. Performance data provided to demonstrate substantial equivalence included detailed dimensional analysis of the subject and predicate device designs, engineering analysis, and mechanical testing of the subject designs. Any differences in the technological characteristics do not raise new issues of safety or efficacy. All of the subject device final finished components are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the previously cleared predicate devices in K102641 and K113733, and therefore are substantially equivalent to the predicates with regard to materials and biocompatibility.

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic designs,
- incorporates the same or very similar materials, and
- has similar packaging and is to be sterilized using the same processes.