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

NEOORTHO Produtos Ortopedicos S/A
Mariana de Oliveira Quinzani
Regulatory Affairs
Rua Ângelo Domingos Durigan, 607, Cascatinha
Curitiba, Paraná 82025-100
Brazil

June 27, 2017

Re: K162874
Trade/Device Name: Cannulated Screws Neoortho
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: May 24, 2017
Received: May 30, 2017

Dear Ms. Mariana de Oliveira Quinzani:

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,

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)*

K162874

Device Name

Cannulated Screws Neoortho

Indications for Use *(Describe)*

The Cannulated Screws Neoortho are generally intended for fracture fixation of various bones and bone fragments, such as femoral neck, intercondylar femoral, malleolus, pilon tibial, calcaneus, talus, tibial plateau, tarsal, metatarsal, wrist, metacarpal, carpal, scaphoid and radius fracture. The Cannulated Screws Neoortho are also intended for fixation arthrodesis, iliosacral dislocations, and hallux valgus corrections. Accessories implants: The washer is used to increase bone contact area for distributing the forces/load and prevent the screw head from sinking into the 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.

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510(k) Summary

NEOORTHO Produtos Ortopédicos S/A

Cannulated Screw Neoortho

September 30, 2016

ADMINISTRATIVE INFORMATION

Manufacturer Name:

NEOORTHO Produtos Ortopédicos S/A
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name : Cannulated Screws Neoortho

Common Names: Smooth or Threaded Metallic Bone Fixation Fastener

Classification Names: Smooth or Threaded Metallic Bone Fixation

Classification Regulations: 21 CFR 888.3040

Product Code: HWC and HTN

Classification Panel: Classification Panel

Reviewing Branch: Joint Fixation Devices Branch Two (JFDB2)

INTENDED USE

The Cannulated Screws Neoortho are generally intended for fracture fixation of various bones and bone fragments, such as femoral neck, intercondylar femoral, malleolus, pilon tibial, calcaneus, talus, tibial plateau, tarsal, metatarsal, wrist, metacarpal, carpal, scaphoid and radius fracture. The Cannulated Screws Neoortho are also intended for fixation arthrodesis, iliosacral dislocations, and hallux valgus corrections. Accessories implants: The washer is used to increase bone contact area for distributing the forces/load and prevent the screw head from sinking into the bone

DEVICE DESCRIPTION

The Neoortho Cannulated Screws include nine cannulated screw specifications and associated washers, which are manufactured from stainless steel and titanium alloy. The cannulated screw is a self-tapping screw with a cancellous or cortical thread that can be guided into a position via a guided wire. They are used to aid in the alignment and stabilization of fractures to the skeletal system.

The technological characteristic of the Neoortho Cannulated Screws are similar to the predicate devices including design, dimensions, and materials. The Neoortho cannulated screws and washers are fabricated from stainless steel per ASTM F138 and Ti-6Al-4V alloy per ASTM F136. The stainless steel and Ti-6Al-4V are commonly used material in orthopedic implants.

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:

K142057, Infix Medical LLC, Infix Cannulated Screw System

K050636, Synthes (USA), Synthes (USA) 3.0 mm Headless Compression Screws

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. 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.

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.

The basis for the belief of NEOORTHO Produtos Ortopédicos S/A that the subject device is substantially equivalent to the predicate devices is summarized in the following pages. Specific comparisons of the subject device to the predicate devices, arranged by screw designs, predicate 510(k) information, and predicate marketing information also are provided in this section.

SUMMARY OF PERFORMANCE DATA (NONCLINICAL AND CLINICAL TEST)

Non-clinical tests

- The biomechanical tests ASTM F543 and ASTM F1264 were performed to determine substantial equivalence of the Cannulated Screws Neoortho including self-tapping, torsional, axial pullout, driving torque, bending and fatigue. Results indicate that de subject screws are substantially equivalent to legally market devices offering a reasonable assurance of safety and effectiveness.

- The cleaning validation was performed in according with the AAMI TIR 30: 2011 and NBR 14332: 1999. The tests results show that the acceptance criteria are met.
- The sterilization process parameters are validate for the sterility assurance level of (SAL) de 10^{-6} (AAMI-ST79: 2010/A4 and BS EN ISO 17665-1). The tests results show that the acceptance criteria are met.
- The Cannulated Screw Neoortho has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Cannulated Screw Neoortho in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLINICAL TESTS

Clinical data and conclusions were not needed for these devices to show substantial equivalence.

CONCLUSION

The Cannulated Screws Neoortho has been shown to be substantially equivalent the predicate devices. Result of preclinical tests/engineering justification and similarities with the legal market predicated devices indicate the device will perform within the intended use and no new issues of safety or effectiveness have been raised.