December 6, 2022

Neoortho Produtos Ortopédicos S/A
Luciane Suzuki
Regulatory Affairs
Rua Ângelo Domingos Durigan, 607 , Cascatinha
Curitiba, PR 82025-100
Brazil

Re: K221021
Trade/Device Name: Femoral Trochanteric Nail System - Neonail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 10, 2022
Received: October 11, 2022

Dear Luciane Suzuki:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Victoria A. Lilling -S Digitally signed by Victoria A. Lilling -S Date: 2022.12.06 07:53:38 -05'00'

Victoria Lilling, M.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221021

Device Name
Femoral Trochanteric Nail System – Neonail

Indications for Use *(Describe)*
The Femoral Trochanteric Nail System – Neonail is indicated for the treatment of stable and unstable fractures as well as for stabilization of bones and correction of bone deformities in the intracapsular, trochanteric, subtrochanteric and shaft regions of the femur.

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 SA

Femoral Trochanteric Nail System – Neonail

December 05, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name: Neoortho Produtos Ortopédicos SA
Rua Ângelo Domingos Durigan, 607
Curitiba, PR 82025-100
Brazil
Office number: +55 41 3535 1033

Official Contact: Luciane Suzuki
Regulatory Affairs
Email: regulatorio@neoortho.com.br

DEVICE NAME AND CLASSIFICATION

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	Femoral Trochanteric Nail System – Neonail
Common or Usual Name:	Rod, fixation, intramedullary and accessories
Classification Name	Intramedullary fixation rod
Regulation Number:	21 CFR 888.3020
Product Code:	HSB
Class of Device:	Class II
Panel:	Orthopedic Products Panel
Reason for Submission:	New device
Prior Related Submissions:	K151806
Multiple Devices:	None; this is the only device in the submission

INTENDED USE

Femoral Trochanteric Nail System – Neonail system is intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved. It is intended for adults only.

INDICATIONS FOR USE

Device Name: Femoral Trochanteric Nail System – Neonail

The Femoral Trochanteric Nail System – Neonail is indicated for the treatment of stable and unstable fractures as well as for stabilization of bones and correction of bone deformities in the intracapsular, trochanteric, subtrochanteric and shaft regions of the femur.

The subject device Femoral Trochanteric Nail System – Neonail has the following differences regarding the INDICATIONS FOR USE when compared with the predicate device cleared in K200869:

- The subject device is not indicated in cases including osteoporotic and osteopenic bone;
- The subject device does not include a "U-Blade Lag Screw" to be indicated for rotationally unstable fractures.

However, the subject device indications for use are totally included in the indications of the predicate device, that is, the subject indications are an identical subset of the predicate indications. The differences are related to the additional "U-Blade Lag Screw" present only in the predicate system. The subject device is not intended to cover the functions of the predicate additional "U-Blade Lag Screw". Thus, the differences do not raise new concerns regarding the safety and effectiveness of the subject device.

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. Femoral Trochanteric Nail System – Neonail consists of metal rods, bone screws, and end caps. 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.

SUBSTANTIAL EQUIVALENCE TO MARKETED DEVICE

510(k)	Manufacturer	Device Name	Predicate
K200869	Stryker Orthopaedics	Gamma®3 Nail System	Primary
K141103	Neoortho Produtos Ortopédicos	Intramedullary Nail and Screws - NEONAIL	Additional

Femoral Trochanteric Nail System – Neonail is substantially equivalent in indications, design, and dimensions to those cleared in K200869.

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 the Femoral Trochanteric Nail System – 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) and ASTM F384-17 *Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices* (static bending and bending fatigue). Cut-out testing was also performed for the Trochanteric Nail/Trochanteric Sliding Screw construct based on the article by SOMMERS et al., 2004[1].

The worst case screws available in the Femoral Trochanteric Nail System – 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

[1] SOMMERS, M. B.; ROTH, C.; HALL, H.; KAM, B. C. C.; EHMKE, L. W.; KRIEG, J. C.; MADEY, S. M.; BOTTLANG, M. A Laboratory Model to Evaluate Cutout Resistance of Implants for Pertrochanteric Fracture Fixation. Journal of Orthopaedic Trauma, v. 18, n. 6, p. 361–368, 2004.

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.

The differences in technological characteristics between the subject and predicate devices are related to the additional "U-Blade Lag Screw" present only in the predicate system. However, the other components of both systems are substantially equivalent. The subject device is not intended to cover the functions of the predicate additional "U-Blade Lag Screw". Thus, 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, Femoral Trochanteric Nail System – Neonail is substantially equivalent 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.