Ortho Development® Corporation
Drew Weaver
Director of Regulatory Affairs
12187 South Business Park Drive
Draper, Utah 84020

December 21, 2021

Re: K211086
Trade/Device Name: The Progen™ Trochanteric Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDS
Dated: November 23, 2021
Received: November 24, 2021

Dear Drew Weaver:

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,

For Jiping Chen, Ph.D., M.P.H.
Acting Division 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)*
K211086

Device Name
The Progen™ Trochanteric Nail System

Indications for Use *(Describe)*
The Progen™ short trochanteric nail is indicated for fixation of various types of stable and unstable neck, intertrochanteric, and peritrochanteric fractures.

The Progen™ long trochanteric nail is intended for fixation of stable and unstable femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10cm proximal to the intercondylar notch including fractures of the basilar neck, intertrochanteric fractures, peritrochanteric fractures, subtrochanteric fracture, femoral shaft fractures, pathological fractures, impending pathological fractures, tumor resection, nonunion, malunion, and revisions.

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Name of the Sponsor:	Ortho Development® Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Primary Contact:	Name: Drew Weaver Position: Director of Regulatory and Clinical Affairs Telephone: (801) 619-3419 Email: dweaver@orthodevelopment.com
510(k) Secondary Contact:	Name: Stan Despres Position: V.P. Product Development Telephone: (801) 376-6231 Email: stan@orthodevelopment.com
Date Prepared:	December 14, 2021
Submission Type:	Traditional 510(k)
Proprietary Name:	The Progen™ Trochanteric Nail System
Common Name:	Intramedullary fixation rod and accessories
Classification:	21 CFR 888.3020
Device Class:	Class II
Device Product Code:	HSB, JDS
Primary Predicate Device:	Gamma3® Nail System (K043431)
Secondary Predicate Device:	TriGen InterTAN (K040212)

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5.1 Device Description:

The Progen™ Trochanteric Nail System consists of temporary fixation intramedullary nails and their accompanying instrumentation designed for fracture fixation and stabilization of the femur. The implants are available in various lengths and diameters to accommodate a range of patient anatomy. Each of the intramedullary nails is secured by a sequence of screws that transect through holes in the proximal and distal sections of each nail.

The Progen™ Trochanteric Nail System consists of single-use intramedullary nails for stable and unstable neck, intertrochanteric, pertrochanteric, and subtrochanteric fractures and combinations of these fractures. The system consists of Nail, Lag Screw, Secondary Screw, Lag Cap, Locking Screws, Set Screws, and Nail End Cap. The nails and accompanying components are manufactured from titanium alloy (Ti-6Al-4V ELI). Additionally, the Nails and Lag Screws have a Type II anodized surface treatments.

5.2 Indication for Use:

The Progen™ short trochanteric nail is indicated for fixation of various types of stable and unstable neck, intertrochanteric, and peritrochanteric fractures.

The Progen™ long trochanteric nail is intended for fixation of stable and unstable femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10cm proximal to the intercondylar notch including fractures of the basilar neck, intertrochanteric fractures, peritrochanteric fractures, subtrochanteric fracture, femoral shaft fractures, pathological fractures, impending pathological fractures, tumor resection, nonunion, malunion, and revisions.

5.3 Comparison of Technological Characteristic:

The Progen™ Trochanteric Nail System is technologically similar to the already cleared predicate device Gamma3® Nail System (K043431) and TriGen InterTAN (K040212) in terms of indication for use/ intended use, technological characteristics, basic design, device material, mechanical performance and principle of operation.

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5.4 Performance Data:

Sterilization

The Progen™ Trochanteric Nail System is gamma radiation sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the following standards:

- ISO 11137-1:2006, Am1:2013, Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization; and
- ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.

Validation results indicate that the Progen™ Trochanteric Nail System complies with the standards.

Shelf Life

The packaging of The Progen™ Trochanteric Nail System was validated in accordance with the following standards:

- ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems; and
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.

Validation results indicate that the packaging for the Progen™ Trochanteric Nail System complies with the standards.

Biocompatibility

The Progen™ Trochanteric Nail System contact materials were verified in accordance with the following standards:

- ISO 10993-1:2009, Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process.

Validation results indicate that the biological evaluation complies with the standard.

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Mechanical Testing

The following mechanical testing were performed on The Progen™ Trochanteric Nail System

- Full construct fatigue cantilever loading test per ASTM F384:2017
- Full construct static cantilever loading test per ASTM F384:2017
- Bone screw axial pullout strength test per ASTM F543:2017
- Bone screw driving torque per ASTM F543:2017
- Bone screw torsional properties test per ASTM F543:2017
- Static Four-Point bend test per ASTM F1264:2016(e1)
- Bending Fatigue test per ASTM F1264:2016(e1)
- Static Torsional Stiffness Test ASTM F1264:2016(e1)

Clinical Testing

None provided for basis of substantial equivalence.

5.5 Substantial Equivalence Conclusion:

Verification and Validation activities were conducted to establish the performance of The Progen™ Trochanteric Nail System. The results of these activities demonstrate that The Progen™ Trochanteric Nail System is as safe, as effective, and performs as well as legally marketed predicates.

Bases on similarities in indication for use/intended use, technological characteristic, basic design, device material, and principle of operation, The Progen™ Trochanteric Nail System is considered substantially equivalent to the previously cleared predicate devices.