X-Bolt Orthopedics
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
Mcra, LLC
803 7th Street, NW, 3rd Floor
Washington, District of Columbia 20001

March 6, 2023

Re: K221621
Trade/Device Name: Pro-X1™ Trochanteric Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 31, 2023
Received: January 31, 2023

Dear Hollace Rhodes:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.03.06 18:58:04 -05'00'

For Jiping Chen, MD, PhD, MPH
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)*

K221621

Device Name
Pro-X1™ Trochanteric Nailing System

Indications for Use *(Describe)*
The Pro-X1™ Trochanteric Nailing System is intended for use in fracture fixation in the femur in adults with osteopenia or osteoporosis. The Pro-X1™ Trochanteric Nailing System is indicated for use in:

- Intertrochanteric and subtrochanteric fractures
- Segmental fractures
- Comminuted fractures
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union, and delayed union
- Surgically created defects such as osteotomies

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

Manufacturer: X-Bolt Orthopedics
Unit 5
Northwood Court
Santry, Dublin 9
Ireland
Phone: 353 1 4433880

Contact: Brian Thornes, MCh FRCSI MBA, CEO
Email: brian.thornes@x-bolt.com

Prepared by: MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001

Date Prepared: March 3, 2023

Device Trade Name: Pro-X1™ Trochanteric Nailing System

Common Name: Intramedullary Fixation Rod

Classifications: 21 CFR 888.3020

Class: II

Product Code: HSB

Indications for Use:
The Pro-X1™ Trochanteric Nailing System is intended for use in fracture fixation in the femur in adults with osteopenia or osteoporosis. The Pro-X1™ Trochanteric Nailing System is indicated for use in:

- Intertrochanteric and subtrochanteric fractures
- Segmental fractures
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- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union, and delayed union
- Surgically created defects such as osteotomies

Device Description:
The Pro-X1™ Trochanteric Nailing System is a single use device intended for long-term implantation into the femur. The Pro-X1™ Trochanteric Nailing System consists of the following components:

- **Pro-X1™ Expanding Bolt:** is a metal expanding hip bolt available in various lengths.
- **Pro-X1™ Trochanteric Nail:** is a metal intramedullary (IM) nail which is designed to be used in conjunction with the Pro-X1™ Expanding Bolt to provide fixation of fractures of the femur. It is available in various lengths, in right and left configurations.
- **Set-Screw:** The set-screw prevents the Pro-X1™ Expanding Bolt from rotating, while still allowing for dynamic movement.
- **Interlocking Screws:** The interlocking screws are used in conjunction with the Pro-X1™ Trochanteric Nail to achieve distal fixation of the nail. The interlocking screws are available in various lengths.

Predicate Device:
X-Bolt Orthopedics' X-BOLT IM Hip Nail System (K181640); 21 CFR 888.3020; Class II

Reference Device:
Howmedica Osteonics Corp.'s Gamma 3 Nail System (K034002); 21 CFR 888.3020; Class II

Substantial Equivalence:
The subject device is substantially equivalent to the predicate X-BOLT IM Hip Nail System (K181640) with respect to intended use, indications, design, function, manufacturing, and performance. The information summarized in the Design Control Activities Summary demonstrates that the Pro-X1™ Trochanteric Nailing System met the pre-determined acceptance criteria for the verification activities.

Non-Clinical Performance Data:
Performance testing included:

- Gliding hip nail fatigue test (PI-19 based on ISO 7206-4)
- Static four-point bending test per ASTM F1264
- Dynamic four-point bending test per ASTM F1264
- Torsional yield testing of the bone screw per ASTM F543
- Insertion torque testing of the bone screw per ASTM F543
- Pull-out testing of the bone screw per ASTM F543
- Torque testing to expand X-Bolt
- Fatigue bending strength testing of X-Bolt
- Characterization of coating adhesion

Results of the bench performance testing and analyses demonstrate that the Pro-X1™ Trochanteric Nailing System is as safe and effective, and performs as well as the predicate X-BOLT IM Hip Nail System (K181640).

Substantial Equivalence Conclusion:
Substantial equivalence of the Pro-X1™ Trochanteric Nailing System to the X-BOLT IM Hip Nail System (K181640) is based on the following:

- Both devices have the same intended use
- Both devices operate using the same fundamental scientific technology
- Both devices share similar functional and technological characteristics via similar operational principles

Evaluation of the risk and performance data referenced in this 510(k) submission demonstrate that the subject Pro-X1™ Trochanteric Nailing System is as safe and effective for its intended use and is substantially equivalent to the X-BOLT IM Hip Nail System.