X-Bolt® Orthopaedics
Dr. Brian Thornes
Founder & CEO
Unit 5, Northwood Court
Dublin, IE

October 12, 2018

Re: K181640
Trade/Device Name: X-BOLT® Hip Fracture Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, KTT
Dated: June 21, 2018
Received: June 21, 2018

Dear Dr. Brian Thornes:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.10.12 15:54:43 -04'00'

For 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)*
K181640

Device Name
X-BOLT® Hip Fracture Fixation System

Indications for Use *(Describe)*
The X-BOLT® IM Hip Nailing System is intended for use in fracture fixation in the femur in adults with osteopenia or osteoporosis. The X-BOLT® IM Hip 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

The X-BOLT® Dynamic Hip Plating System is intended for use in fracture fixation in the proximal femur in adults with osteopenia or osteoporosis. The X-BOLT® Dynamic Hip Plating System is indicated for use in:

- Intracapsular and extracapsular fractures of the femoral neck
- Trochanteric fractures of the proximal femur
- Stable subtrochanteric fractures of the proximal 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 for
X-BOLT® Hip Fracture Fixation System

1. Submission Sponsor

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2. Prepared by

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3. **Date Prepared**

October 3, 2018

4. Device Name

Trade/Proprietary Name:	X-BOLT® Hip Fracture Fixation System
Common/Usual Name:	Trochanteric Nail and Dynamic Hip Plating System
Classification Name:	Intramedullary fixation rod; Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Single/Multiple Component Metallic bone fixation appliances and accessories.
Classification Regulation:	21 CFR 888.3020 and 21 CFR 888.3030
Classification Panel:	Orthopedics
Product Code:	HSB, KTT
Device Class:	II

5. Predicate and Reference Devices

The X-BOLT® Hip Fracture Fixation System is substantially equivalent to the Zimmer Natural Nail System (K083497, K091566, K120715), Smith & Nephew Asian Intramedullary Hip Screw Nails [IMHS] (K050226), Smith & Nephew Compression Hip Screw System (K993289, K921786, and K895241), and Stryker Howmedica Osteonics Omega 3 System (K062066) based on similarities in intended use, technological characteristics, and performance data. The PERI-LOC Proximal Femur

Locking Bone Plate System (K072818) serves as a predicate device based on similar technological characteristics and the same intended use.

6. Device Description

IM Hip Nailing System

The X-BOLT® IM Hip Nailing System is a single use device intended for long-term (greater than 30 days) implantation into the femur. The X-BOLT® IM Hip Nailing System consists of the following components.

A. X-BOLT®: The X-BOLT® is an expanding hip bolt available in various sizes.

B. X-BOLT® IM Hip Nail: The X-BOLT® IM Hip Nail is a metal nail which is designed to be used in conjunction with the X-BOLT® to provide fixation of fractures of the femur. It is available in various lengths, in right and left configurations.

C. End-Cap: End-Caps prevent bone ingrowth into the proximal end of the nail.

D. Set Screw: The set screw prevents the X-BOLT® from rotating, while still allowing for dynamic movement.

E. X-BOLT® Distal Locking Screws: The X-BOLT® Distal Locking Screws are bone fixation screws which are designed to be used in conjunction with the X-BOLT® IM Hip Nail to achieve distal fixation of the nail. The X-BOLT® Distal Locking Screws are available in various lengths.

Dynamic Hip Plating System

The X-BOLT® Dynamic Hip Plating System is a single use device intended for long-term (greater than 30 days) implantation into the proximal femur. The X-BOLT® Dynamic Hip Plating System consists of the following components.

A. X-BOLT®: The X-BOLT® is an expanding hip bolt available in various sizes.

B. X-BOLT® Dynamic Hip Plate: The X-BOLT® Dynamic Hip Plate is an angled metal plate which is designed to be used in conjunction with the X-BOLT® to provide fixation of fractures of the proximal femur. It is available in various sizes.

C. X-BOLT® Cortical Screws: The X-BOLT® Cortical Screws are bone fixation screws which are designed to be used in conjunction with the X-BOLT® Dynamic Hip Plate to provide fixation of fractures of the proximal femur. The X-BOLT® Cortical Screws are available in various lengths.

7. Intended Use

IM Hip Nailing System

The X-BOLT® IM Hip Nailing System is intended for use in fracture fixation in the femur in adults with osteopenia or osteoporosis. The X-BOLT® IM Hip 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

Dynamic Hip Plating System

The X-BOLT® Dynamic Hip Plating System is intended for use in fracture fixation in the proximal femur in adults with osteopenia or osteoporosis.

The X-BOLT® Dynamic Hip Plating System is indicated for use in:

- Intracapsular and extracapsular fractures of the femoral neck
- Trochanteric fractures of the proximal femur
- Stable subtrochanteric fractures of the proximal femur

8. Technological Characteristics and Substantial Equivalence

The following tables compares the X-BOLT® Hip Fracture Fixation system to the respective predicate devices. The table below compares the IM Hip Nailing System to the Zimmer Natural Nail System (K083497; K091566; K120715) with respect to intended use, technological characteristics and principles of operation to support a determination of substantial equivalence for the X-BOLT® device.

Comparison Table: X-BOLT® IM Hip Nailing System vs. Zimmer Natural Nail System

Manufacturer	**X-BOLT® Orthopaedics**	**Zimmer**
Trade Name	X-BOLT® IM Hip Nailing System	Zimmer® Natural Nail™ System
510(k) Number	Subject device	K083497; K091566; K120715
Product Code	HSB	HSB
Regulation Number	21 CFR 888.3020	21 CFR 888.3020
Classification	II	II
Indications for use:	The X-BOLT® IM Hip Nailing System is intended for use in fracture fixation in the femur in the adult population. The X-BOLT® IM Hip Nailing System is indicated for use in: • Intertrochanteric and subtrochanteric fractures • Segmental fractures • Comminuted fractures • Fractures involving osteopenic and osteoporotic bone • Pathological fractures • Fractures with bone loss • Pseudoarthrosis, non-union, mal-union, and delayed union • Surgically created defects such as osteotomies	The Zimmer® Natural Nail™ System is intended for temporary fixation and stabilization of the bone. Indications for use of the greater Trochanter and Piriformis Fossa nails in the femur include: • Compound and simple shaft fractures • Proximal, metaphyseal, and distal shaft fractures • Segmental fractures • Comminuted fractures • Fractures involving osteopenic and osteoporotic bone • Pathological fractures • Fractures with bone loss • Pseudoarthrosis, non-union, mal-union, and delayed union • Periprosthetic fractures • Surgically created defects such as osteotomies • Intertrochanteric and subtrochanteric fractures
Components and Design	• Intramedullary Nail, Fixation Bolt, Distal Screws • Achieves fixation via four expanding wings that expand precisely into premade cavities and are designed to resist cut-out	• Intramedullary nail, Lag Screw, and Distal Screw • Achieves fixation via a threaded sliding lag screw
Materials	Implant grade stainless steel Parylene C Coating	Titanium Alloy (Ti-6Al-4V)

The table below compares the X-BOLT® Dynamic Hip Plating System to the Stryker Howmedica Osteonics Omega 3 System (K062066) with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Comparison Table: X-BOLT® Dynamic Hip Plate vs. Stryker Howmedica Osteonics Omega 3 System

Manufacturer	**X-BOLT® Orthopaedics**	**Stryker Howmedica Osteonics**
Trade Name	X-BOLT® Dynamic Hip Plating System	Omega 3 System
510(k) Number	Subject device	K062066
Product Code	KTT	KTT
Regulation Number	21 CFR 888.3030	21 CFR 888.3030
Classification	II	II
Indications for use:	The X-BOLT® Dynamic Hip Plating System is intended for use in fracture fixation in the proximal femur in the adult population. The X-BOLT® Dynamic Hip Plating System is indicated for use in: • Intracapsular and extracapsular fractures of the femoral neck • Trochanteric fractures of the proximal femur • Stable subtrochanteric fractures of the proximal femur	The Omega (Systems) are intended for use in the temporary stabilization of types of fractures to the proximal and distal femur. The subject devices are indicated for fixation of proximal and distal femoral fractures including but not limited to: • Intracapsular and basal neck fractures including transcervical and subcapital fractures • Intertrochanteric fractures • Subtrochanteric fractures • Supracondylar fractures • Osteotomies for patients with diseases or deformities of the hip • Hip arthrodesis
Components and Design	• Implant grade stainless steel plate, screws and fixation bolt • Achieves fixation via four expanding wings that expand precisely into premade cavities and are designed to resist cut-out	• Implant grade stainless steel plate, screws and lag screw • Achieves fixation via a threaded sliding lag screw
Materials	Implant grade stainless steel Parylene-C coating	Implant grade stainless steel
Sterility	Sterile (irradiation)	Sterile

Manufacturer	X-BOLT® Orthopaedics	Stryker Howmedica Osteonics
Trade Name	X-BOLT® Dynamic Hip Plating System	Omega 3 System
Dimensions	The X-BOLT® is an expanding hip bolt available in 10 different lengths ranging from 80mm to 125mm in 5mm increments. The X-BOLT® Dynamic Hip Plate is a 135^{o} angled metal plate and is available in four different sizes – 2-hole, 4- hole, 5-hole and 6-hole configurations. X-BOLT® Cortical Screws are 4.5mm in diameter and available in 10 different sizes from 30mm to 48mm in 2mm increments	The Omega 3 bolt is available in various sizes ranging from 50mm to 140 mm in 5mm increments The Omega 3 system plate is available in keyed and keyless configurations, in short and standard barrel options, ranging from 2 hole to 12 holes, with multiple options for plate angles (130 – 150^{o}) and in lengths from 47 – 207mm. Omega cortical screws are 4.5mm in diameter and available in 14-110 mm in 2-5mm increments. Other locking screws also offered (14-95mm).

9. Performance Testing

The X-BOLT® Hip Fracture Fixation System underwent the following testing which supports its substantial equivalence to predicate devices:

- ASTM F1264-03:2012 – *Standard specification and test methods for intramedullary fixation devices.*
- ASTM F384-06:2006 – *Standard specifications and test methods for metallic angled orthopedic fracture fixation devices*.
- ISO 7206-04:2002 –*Partial and Total Hip Joint Prostheses – Part 4: Determination of Endurance Properties of Stemmed Femoral Components.*
- ASTM F543-07 – Standard specification and test methods for metallic medical bone screws.
- Cadaver testing to evaluate the post-implantation strength of the femoral head
- Cut-out strength of device from femoral head
- Simulated expansion testing of the X-Bolt device
- Pyrogen LAL testing

The results of all testing of the X-BOLT® Hip Fracture Fixation System demonstrate that it performs comparably to predicate devices, thereby supporting its substantial equivalence.

10. Biocompatibility Testing

The X-BOLT® Hip Fracture Fixation System was tested in accordance with ISO 10993 to demonstrate its biocompatibility.

- Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- Part 5: Tests for in vitro cytotoxicity
- Part 6: Tests for local effects after implantation
- Part 10: Tests for irritation and delayed-type hypersensitivity
- Part 11: Tests for Systemic Toxicity

11. Conclusion

This 510(k) submission demonstrates the substantial equivalence of the X-BOLT® Hip Fracture Fixation System to the referenced predicate devices.