OrthoXel DAC
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors LLC
803 7th Street NW
3rd Floor
Washington, District of Columbia 20001

April 4, 2024

Re: K233910
Trade/Device Name: Vertex Hip Fracture Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 12, 2024
Received: February 12, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.04.04 09:20:02 -04'00'

for: Farzana Sharmin, PhD
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)*
K233910

Device Name
Vertex Hip Fracture Nailing System

Indications for Use *(Describe)*
The Vertex Hip Fracture Nailing System is intended for temporary fixation and stabilization of stable and unstable fractures of the proximal femur. The Vertex Nail is indicated for use in adult patients for treatment of:
• Pertrochanteric fractures;
• Intertrochanteric fractures;
• High subtrochanteric fractures
• Combinations of the above fractures, including non-union, malunion and tumor resections.

The Long Nail system is additionally indicated for use in adult patients for treatment of:
• Pertrochanteric fractures associated with shaft fractures;
• Pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas;
• Impending pathological fractures;
• Long subtrochanteric fractures;
• Ipsilateral femoral fractures;
• Proximal or distal non-unions, malunions, revision procedures and tumor resections.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Manufacturer

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2. Primary Correspondent

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3. Secondary Correspondent

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4. Date Prepared

28 March 2024

5. Device Name and Classification Information

Trade/Proprietary Name: Vertex Hip Fracture Nailing System

Common/Usual Name: Hip Fracture Nail

Classification Name: Intramedullary Fixation Rod

Classification Regulation: 21 CFR 888.3020

Medical Specialty: Orthopedics

Product Codes: HSB

Device Class: II

6. Predicate Devices

The Vertex Hip Fracture Nailing System is substantially equivalent to the primary predicate, the Zimmer Biomet Affixus Hip Fracture Nail (K183162), and the TriGen InterTAN (K040212) with respect to intended use, technological characteristics, and performance data.

7. Device Description

The Vertex Hip Fracture Nailing (HFN) System is a cephalomedullary fixation system designed to be implanted and interlocked proximally and distally using bone screws by means of a provided surgical instrumentation kit. Like many of the currently marketed intramedullary nails, the Vertex HFN offers several different proximal and distal locking options from which the surgeon may choose, depending on the nature of the fracture. The Vertex HFN System includes long and short cephalomedullary nails, lag screws, bone screws, and endcaps all of varying lengths and diameters. All parts of the system are manufactured from Titanium 6AL4VELi.

8. Indications for Use

The Vertex Hip Fracture Nailing System is intended for temporary fixation and stabilization of stable and unstable fractures of the proximal femur. The Vertex Nail is indicated for use in adult patients for treatment of:

- Pertrochanteric fractures;
- Intertrochanteric fractures;
- High subtrochanteric fractures
- Combinations of the above fractures, including non-union, malunion and tumor resections.

The Long Nail system is additionally indicated for use in adult patients for treatment of:

- Pertrochanteric fractures associated with shaft fractures;
- Pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas;
- Impending pathological fractures;
- Long subtrochanteric fractures;
- Ipsilateral femoral fractures;
- Proximal or distal non-unions, malunions, revision procedures and tumor resections.

9. Technological Characteristics and Substantial Equivalence

The Vertex Hip Fracture Nailing System is substantially equivalent to the predicate device, the Zimmer Biomet Affixus Hip Fracture Nail (K183162), based on the following:

- Intended Use: Both systems are intended for use in the stabilization of fractures in the proximal femur.
- Design: Both systems employ an intramedullary nail, lag screw, optional proximal stabilizing screws, and distal interlocking screws.
- Materials: Both systems are made of titanium alloy.
- Dimensions: The nails, lag screws, and supplemental screws are available in the same range of lengths and diameters as the predicate or other legally marketed devices.

Evaluation of the associated risks do not raise different or new questions of safety or effectiveness. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, the Vertex Hip Fracture Nailing System is substantially equivalent to the predicate device.

10. Reference Devices

OrthoXel's Apex Femoral Nailing System (K181375) and Apex Tibial Nailing System (K170972) are included as reference devices based on similarities in raw materials, manufacturing steps and reagents, technological characteristics, and performance data.

11. Non-Clinical Performance Testing

All necessary testing has been performed for the worst-case configuration of the Vertex Hip Fracture Nailing System to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended. The performance of Vertex Hip Fracture Nailing System was characterized through the following tests:

- Static and Dynamic Axial Compression testing on the full construct using a test method adapted from ISO 7206-4 (this test method is also substantially similar to that in ASTM F384).
- Cutout Testing using an approach described in the scientific literature (there is no applicable ISO/ASTM/AAMI standard).
- Engineering Rationale per ASTM F1264-16 and ASTM F543-07

12. Conclusion

The Vertex Hip Fracture Nailing System possesses the same intended use and technological characteristics as the predicate device. Therefore, the Vertex Hip Fracture Nailing System is substantially equivalent for its intended use.