December 20, 2017
OrthoXel
% Hollace Rhodes
Director, Orthopedic Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K170972
Trade/Device Name: Apex Tibial Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: November 20, 2017
Received: November 20, 2017

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Vincent J. Devlin -S

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)*

K170972

Device Name

Apex Tibial Nailing System

Indications for Use *(Describe)*

The Apex Tibial Nailing system is intended for temporary fixation and stabilization of the fractures of the tibia. The Apex nail is indicated for used in adult patients for treatment of:

- Open and closed tibial fractures, including simple, severely comminuted, spiral, large oblique, and segmental fractures;
- Fractures involving osteopenic or osteoporotic bone;
- Fractures with bone loss;
- Pseudoarthosis, nonunion, and malunion;
- Correction osteotomy;
- Pathologic fractures and prophylactic nailing of impending pathologic fractures; and
- Reconstruction following tumour resection.

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 Apex Tibial Nailing System

1.1 Submission Sponsor

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1.2 Prepared by

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1.3 Date Prepared

18 December 2017

1.4 Device Name

1.4.1	Trade/Proprietary Name:	Apex Tibial Nailing System
1.4.2	Common/Usual Name:	Tibial Nail
1.4.3	Classification Name:	Intramedullary Fixation Rod
1.4.4	Classification Regulation:	21 CFR 888.3020
1.4.5	Classification Panel:	Orthopedics
1.4.6	Product Codes:	HSB, HWC
1.4.7	Device Class:	II

1.5 Predicate Devices

The System is substantially equivalent to the Biomet Tibial Locking Nail System (K063570), the Zimmer Natural Nail (K082770), and L.T.S. IM Nail Systems CFN-CTN-CHN (K132945) based on similarities in intended use, technological characteristics, and performance data.

1.6 Device Description

The Apex Tibial Nailing System is a tibial intramedullary fixation system designed to be implanted and interlocked proximally and distally using bone screws by means of a provided reusable surgical instrumentation kit. Like many of the currently-marketed intramedullary nails, the Apex Nail offers several different proximal and distal locking options from which the surgeon may choose, depending on the nature of the fracture. An insert within the proximal nail stem maintains the torsional stability of static locking when the construct is locked in a dynamization mode. The Apex Tibial Nailing System includes a tibial nail, bone screws and endcaps of varying sizes. All parts of the system are manufactured from Titanium 6AL4VELi. The Apex Tibial Nail, screw and endcap are available in varying lengths and diameters.

1.7 Intended Use

The Apex Tibial Nailing System is intended for temporary fixation and stabilization of the fractures of the tibia. The Apex nail is indicated for used in adult patients for treatment of:

- Open and closed tibial fractures, including simple, severely comminuted, spiral, large oblique, and segmental fractures;
- Fractures involving osteopenic or osteoporotic bone;
- Fractures with bone loss;
- Pseudoarthrosis, nonunion, and malunion;
- Correction osteotomy;
- Pathologic fractures and prophylactic nailing of impending pathologic fractures; and
- Reconstruction following tumour resection.

1.8 Technological Characteristics and Substantial Equivalence

The Apex Tibial Nailing System is substantially equivalent to the predicate devices, the Biomet Tibial Locking Nail System, the Zimmer Natural Nail, and the L.T.S. IM Nail Systems CFN-CTN-CHN with respect to intended use, technological characteristics (components, materials, overall design, and dimensions), sterility, and principles of operation.

1.9 Non-Clinical Performance Testing

The Apex Tibial Nailing System was tested in accordance with the following standards and all acceptance criteria were met:

- ASTM F1264-16 – Standard specification and test methods for intramedullary fixation devices.
- ASTM F543-07 – Standard specification and test methods for metallic medical bone screws.
- Full construct fatigue testing

1.10 Conclusion

This 510(k) submission supports the substantial equivalence of the Apex Tibial Nailing System to the referenced predicate devices.