DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 26, 2016

Conventus Orthopaedics, Incorporated
Mr. Kent R. Lind
Vice President, Quality, Regulatory, Clinical
10200 73rd Avenue North, Suite 122
Maple Grove, Minnesota 55369

Re: K161048
Trade/Device Name: Conventus Orthopaedics Ulna Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HSB
Dated: June 20, 2016
Received: June 21, 2016

Dear Mr. Lind:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K161048

Device Name
Conventus Orthopaedics Ulna Fixation System

Indications for Use *(Describe)*
The Conventus Orthopaedics Ulna Fixation System is indicated for treatment of distal or proximal ulna fractures when internal fixation is desired, and fracture fragments are not too numerous and/or too small to be stabilized with the use of the device.

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

Company:	Conventus Orthopaedics, Inc. 10200 73rd Avenue North, Suite 122 Maple Grove, MN 55369
Device Trade Name:	Conventus Orthopaedics Ulna Fixation System
Device Common Name:	Ulna fracture fixation system
Contact:	Kent R. Lind Vice President, Quality, Regulatory, Clinical Phone: (763) 515-5003 Fax: (763) 315-4980
Date Prepared:	July 01, 2016
Classification:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3020: Intramedullary fixation rod
Class:	II
Product Codes:	HRS and HSB
Indications for Use:	The Conventus Orthopaedics Ulna Fixation System is indicated for treatment of distal and proximal ulna fractures when internal fixation is desired, and fracture fragments are not too numerous and/or too small to be stabilized with the use of the device.
Device Description:	The Conventus Orthopaedics Ulna Fixation System is an intramedullary device intended for distal and proximal ulna fractures. The Ulna Fixation System is a self-expanding implant which is deployed into the medullary canal and provides a scaffold to which bone fragments are attached using fragment screws. The implant is made from titanium alloy (Ti-6Al-4V ELI) and Nitinol.

Substantial Equivalence: Conventus Orthopaedics has demonstrated that, for purposes of FDA's regulation of medical devices, the Conventus Orthopaedics Ulna Fixation System is substantially equivalent to the following devices that have been previously cleared by the FDA:

- Primary predicate: Synthes T-Plate (Small Fragment Dynamic Compression Locking System) (K000684)
- Synthes Olecranon Osteotomy Nailing System (K073402)
- Conventus DRS™ System (K102689, K131552)
- Conventus PRS™ System (K151379)

This finding is supported by the following pre-clinical tests that have been performed:

- Static and cyclic axial/bend testing
- Static and cyclic torsional testing
- Screw pullout testing
- Corrosion testing
- Wear testing
- Nickel ion release testing
- Surface analysis testing
- Nitinol phase composition
- Nitinol transition temperature (A_f)
- Biocompatibility testing
- Animal Testing
- MRI Testing
- Kinetic Chromogenic Limulus Amebocyte Lysate testing (pyrogenicity)

The results demonstrate that the Ulna Fixation System is substantially equivalent to the legally marketed predicate devices.