



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

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

April 8, 2015

Re: K141737  
Trade/Device Name: Conventus PHS<sup>™</sup> System  
Regulation Number: 21 CFR 888.3020  
Regulation Name: Intramedullary fixation rod  
Regulatory Class: Class II  
Product Code: HSB, HRS  
Dated: March 17, 2015  
Received: March 17, 2015

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 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.

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 yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K141737

Device Name: Conventus PHS™ System

The Conventus Orthopaedics PHS™ System is indicated for the fixation of proximal humerus fractures except when there are too many fracture fragments to repair the articular surface.

Prescription Use   √    
(Part 29 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## 5. 510(k) Summary

**Company:** Conventus Orthopaedics, Inc.  
10200 73<sup>rd</sup> Avenue North, Suite 122  
Maple Grove, MN 55369

**Device Trade Name:** Conventus PHS™ System

**Device Common Name:** Proximal humerus fracture fixation system

**Contact:** Kent R. Lind  
Vice President, Quality, Regulatory, Clinical  
Phone: (763) 515-5003  
Fax: (763) 315-4980

**Prepared By:** Musculoskeletal Clinical Regulatory Advisers, LLC  
1331 H Street, NW, 12<sup>th</sup> Floor  
Washington, DC 20005  
Phone: (202) 552-5800  
Fax: (202) 552-5798

**Date Prepared:** April 3<sup>rd</sup>, 2015

**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:** JDS and HRS

**Indications for Use:** The Conventus Orthopaedics PHS™ System is indicated for the fixation of proximal humerus fractures except when there are too many fracture fragments to repair the articular surface.

**Device Description:** The Conventus PHS™ is an intramedullary device intended to treat proximal humerus fractures. The PHS™ 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 PHS™ System

is substantially equivalent to the following devices that have been previously cleared by the FDA:

- DePuy ACE TiMAX Meta Plate (K983853)
- Synthes Titanium Cannulated Humeral Nail System (K033071)
- Conventus Orthopaedics, Inc. DRS™ System (K102689)

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

- Static and cyclic axial/bend testing
- Static and cyclical 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

The results demonstrate that the PHS™ System is substantially equivalent to the legally marketed predicate devices.