Conventus Orthopaedics, LLC
Amanda Pentecost
RA/QA Engineer
10200 73rd Ave N.
Suite 122
Maple Grove, Minnesota 55369

January 22, 2021

Re: K202858
Trade/Device Name: Flex-Thread™ Distal Fibula Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 21, 2020
Received: December 22, 2020

Dear Amanda Pentecost:

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/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 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 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,

For Michael Owens
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.

Submission Number *(if known)*

K202858

Device Name

Flex-Thread™ Distal Fibula Intramedullary Nail System

Indications for Use *(Describe)*

The Flex-Thread™ Distal Fibula Intramedullary Nail System is intended for use in the fixation of fibula fractures and osteotomies.

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

Contact Details (21 CFR 807.92(a)(1))		
Applicant Name	Conventus Orthopaedics, LLC	
Applicant Address	10200 73rd Ave N. Suite 122 Maple Grove MN 55369 United States of America	
Applicant Contact Telephone	215-323-4029	
Applicant Contact	Dr. Amanda Pentecost	
Applicant Contact Email	apentecost@flowerortho.com	
Device Name (21 CFR 807.92(a)(2))		
Device Trade Name	Flex-Thread™ Distal Fibula Intramedullary Nail System	
Common Name	Rod, Fixation, Intramedullary And Accessories	
Classification Name	Intramedullary Fixation Rod	
Regulation Number	888.3020	
Product Code	HSB	
Legally Marketed Predicate Devices (21 CFR 807.92(a)(3))		
Predicate #	**Predicate Trade Name**	**Product Code**
K172943	Flex-Thread Fibula Pin System	HSB
Device Description Summary (21 CFR 807.92(a)(4))		
The Flex-Thread™ Distal Fibula Intramedullary Nail System is comprised of an intramedullary fixation device with a flexible threaded tip to engage the proximal portion of a fibula and cortical screws to further enhance stability and fixation of the fibula.		
Intended Use/Indications for Use (21 CFR 807.92(a)(5)		
The Flex-Thread™ Distal Fibula Intramedullary Nail System is intended for use in the fixation of fibula fractures and osteotomies.		
Indications for Use Comparison (21 CFR 807.92(a)(5))		
The Flex-Thread™ Distal Fibula Intramedullary Nail System has the same indications for use as the predicate Intrafuse Flex-Thread Fibula Pin System.		
Technological Comparison (21 CFR 807.92(a)(6))		
The functional design intent of the Flex-Thread™ Distal Fibula Intramedullary Nail System is identical to the Flex-Thread Fibula Pin in that the devices are intended to engage the region of the fibula intramedullary canal proximal to the fracture. Dimensional changes to implants and instruments have been made to meet user needs and do not raise new questions related to safety and effectiveness as demonstrated by non-clinical testing. The Flex-Thread™ Distal Fibula Intramedullary Nail features a partially threaded shaft with an additional distal hole and longer screw lengths. The Flex-Thread™ Distal Fibula Intramedullary Nail System also features standard cortex screws, which are available in longer sizes to allow for syndesmosis repair and introduces low-profile locking cortex screws.		
Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))		
Mechanical testing was performed on the modified Flex-Thread™ Distal Fibula Intramedullary Nail System using the same protocols as those used to verify the original Flex-Thread Fibula Pin System design and submitted in K172943. The following analyses were conducted: • Tip Reaction Force • 4-Point Bend per ASTM F1264 • Torque Strength		

- Insertion and Removal Torque

Additionally, simulated use of the Flex-Thread™ Distal Fibula Intramedullary Nail System was used in a cadaver lab to validate the modified design. The results demonstrate that the modified Flex-Thread™ Distal Fibula Intramedullary Nail System is substantially equivalent to the predicate device in safety and performance.