Flower Orthopedics Corporation DBA Conventus Flower
Christina Rovaldi
Sr. Manager, RA/QA
100 Witmer Road
Horsham, Pennsylvania 19044

November 21, 2022

Re: K222390
Trade/Device Name: Flex-Thread™ Ulna Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 26, 2022
Received: October 27, 2022

Dear Christina Rovaldi:

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,

Victoria A. Lilling -S Digitally signed by Victoria A. Lilling -S
Date: 2022.11.21 20:25:53 -05'00'

Victoria Lilling, M.D.
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)*

K222390

Device Name

Flex-Thread™ Ulna Intramedullary Nail System

Indications for Use *(Describe)*

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

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.

510(k) Summary

Prepared on: 2022-11-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Flower Orthopedics Corporation DBA Conventus Flower
Applicant Address	100 Witmer Road Suite 280 Horsham PA 19044 United States
Applicant Contact Telephone	2153234029
Applicant Contact	Mrs. Christina Rovaldi
Applicant Contact Email	crovaldi@flowerortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Flex-Thread™ Ulna 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 (Primary Predicate is listed first)	Product Code
K202858	Conventus Flower Orthopedics Flex-Thread™ Distal Fibula Intrar	HSB
K042135	Synthes (Usa) Elastic Intramedullary Nail (Ein) System (Line Exte	HSB

Device Description Summary

21 CFR 807.92(a)(4)

The Flex-Thread™ Ulna Intramedullary Nail System is comprised of an intramedullary fixation device with a flexible threaded tip to engage the intramedullary canal of the ulnar diaphysis from an antegrade approach and cortical screws to provide stability and articular support in the proximal ulna and olecranon.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both devices are used in the treatment of fractures and osteotomies. The proposed device offers treatment of fractures and osteotomies of the ulna versus the predicate indications which offers the same treatment but for the fibula. The use of the device in a different anatomic area is supported by the additional predicate identified within the same regulation.

Technological Comparison

21 CFR 807.92(a)(6)

This Traditional 510(k) is submitted to introduce a 4.5mm, 5.5mm, 6.5mm and 7.5mm diameter nail in 120mm, 150mm, 180mm, 210mm, 240mm, 270mm and 290mm lengths as well as additional end caps in 10mm and 20mm. The proposed additions to the Flex-Thread™ System have the same technological characteristics as the predicate device Flex-Thread™ System.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Flex-Thread Ulna implants were subjected to several mechanical tests with the intent of proving substantial equivalence to a predicate device. The following tests were identified according to the consensus standard ASTM F1264 - Standard Specification and Test Methods for Intramedullary Fixation Devices:

- Static Four Point Bend
- Static Torsion
- Bending Fatigue
- Bending Fatigue of Interlocking Screws

Additionally, insertion torque and implant tip deflection were considered to evaluate the safety and efficacy of the device.

Not Applicable

Non-clinical performance testing demonstrates that the Flex-Thread™ Ulna Intramedullary Nail System is substantially equivalent to the predicate device