Flower Orthopedics Corporation DBA Conventus Flower
Amanda Pentecost
RA/QA Engineer
100 Witmer Road
Horsham, Pennsylvania 19044

July 23, 2021

Re: K212030
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: June 28, 2021
Received: June 29, 2021

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)*

K212030

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	Flower Orthopedics Corporation DBA Conventus Flower Orthopedics
Applicant Address	100 Witmer Road Suite 280 Horsham PA 19044 United States
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 (Multiple Component PNs)
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	Flex-Thread™ Distal Fibula Intramedullary Nail 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 TM 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)

This Special 510(k) is submitted to introduce a 5.5mm diameter nail in 130mm and 180mm lengths as well as an additional end cap that is 1mm to the Flex-Thread System. The Flex-Thread System have identical indications for use as the predicate device Flex-Thread System.

Technological Comparison

21 CFR 807.92(a)(6)

The only difference between the predicate device and the subject device is the introduction of a larger nail with a diameter of 5.5mm compared to the originally cleared 3.5mm and 4.5mm diameter nails. Additionally a shorter 1mm end cap has been added to the

predicate offering of 3mm, 5mm and 10mm.

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 Flex-Thread™ Distal Fibula Intramedullary Nail System design as part of K202858. These tests included Tip Reaction Force, Insertion Torque, and Simulated Use Cadaver Lab. Additionally, engineering justifications were provided for 4-Point Bend and Torque Strength testing. The results demonstrate the design inputs meet design outputs and substantial equivalence of the subject device to the predicate.