November 22, 2024

Flower Orthopedics Corporation DBA Conventus Flower Ortho
% Christina Rovaldi
Sr. Manager, RA/QA
Flower Orthopedics Corporation DBA Conventus Flower
100 Witmer Road Suite 280
Suite 280
Horsham, Pennsylvania 19044

Re: K233567
Trade/Device Name: OsteoCoil™ Nitinol Compression System (Multiple Component PNs)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 18, 2024
Received: November 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K233567

Device Name

OsteoCoil™ Nitinol Compression System (Multiple Component PNs)

Indications for Use *(Describe)*

The OsteoCoil™ Nitinol Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of the small bones for wrist, hand, and foot.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K233567

510(k) Summary

Prepared on: 2024-11-18

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	2153231026
Applicant Contact	Mrs. Christina Rovaldi
Applicant Contact Email	crovaldi@flowerortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OsteoCoil™ Nitinol Compression System (Multiple Component PNs)
Common Name	Screw, fixation, bone
Classification Name	Smooth or threaded metallic bone fixation fastener.
Regulation Number	888.3040
Product Code	HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203595	Dynafuse Fixation System	HWC

Device Description Summary

21 CFR 807.92(a)(4)

This Traditional 510(k) is submitted to introduce the OsteoCoil™ Nitinol Compression System. The system consists of a 4.5mm, 6.5mm and 7.3mm screw available in 30mm through 150mm in 5mm increment lengths and appropriate instrumentation to support implantation of the OsteoCoil™ Nitinol Compression screws. The proposed addition of the the OsteoCoil™ Nitinol Compression System have the same technological characteristics as the predicate device, the Dynafuse Fixation System (K203595).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The OsteoCoil™ Nitinol Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of the small bones for wrist, hand, and foot.

Indications for Use Comparison

21 CFR 807.92(a)(5)

This Traditional 510(k) is submitted to introduce a 4.5mm, 6.5mm and 7.3mm screw available in 30mm through 150mm in 5mm increment lengths. The proposed additions have the same technological characteristics as the predicate device Dynafuse Fixation System. The OsteoCoil™ Nitinol Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of the small bones for wrist, hand, and foot.

Technological Comparison

21 CFR 807.92(a)(6)

The difference between the predicate and the subject device is the introduction of additional screw sizes, additionally the proposed device is made entirely of Nitinol while the predicate device is made of a Nitinol core and Titanium Alloy body. Both proposed and

predicates are screw-like devices that use a Nitinol element to achieve sustained compression.

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

Conventus Flower Orthopedic has demonstrated that, for purposes of FDA's regulation of medical devices, the OsteoCoil™ Nitinol Compression System is substantially equivalent supported by the following non-clinical tests that have been performed:

ASTM F543:
- Torsional Strength
- Driving and Removal Torque
- Axial Pullout Strength
- Self-tapping Force

ASRM F1264:
- Bending Fatigue
- Static 4Pt Bending

ASTM F2129
- Pitting Corrosion Testing

ASTM F2004
- Transformation Temperature Testing

Additionally,
- Extension and Compression Force Testing
- Bacterial endotoxin testing based on an endotoxin limit of 20EU/device per ANSI/AAMI ST72:2011
- Applicable testing per ISO 10993

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