August 24, 2026

Flower Orthopedics Corporation DBA Conventus Flower Orthopedics
% Jessica Czamanski
Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Medical Arts Bldg.
Minneapolis, Minnesota 55402

Re: K260106
Trade/Device Name: OsteoCoil™ GT Active Compression System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 12, 2026
Received: January 14, 2026

Dear Jessica Czamanski:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260106

Please provide the device trade name(s).

OsteoCoil™ GT Active Compression System

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K260106 510(K) SUMMARY

I. Submitter

Submitter's Name: Flower Orthopedics Corporation DBA Conventus Flower Orthopedics

Contact Person: Kevin Rzasa

Address: 100 Witmer Road
Suite 280,
Horsham, PA, 19044
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Email: kevin.rzasa@flowerortho.com

Date prepared: August 19, 2026

II. Applicant Correspondent

Contact's Name: DuVal & Associates, P.A.

Contact Person: Jessica Czamanski

Telephone: 754-422-9101

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III. Device

Trade Name: OsteoCoil™ GT Active Compression System

Common Name: Screw, Bone, Fixation

Classification Name: Smooth or threaded metallic bone fixation fastener

Product Classification: Class II

Regulation Number: 21 CFR § 888.3040

Product Code: HWC

IV. Predicate Device

Manufacturer: Conventus Flower Orthopedics

Device Name: OsteoCoil™ Nitinol Compression System

510(k) Number: K233567

Product Classification: Class II

Regulation Number: 21 CFR § 888.3040

V. Device Description

The proposed device is comprised of dynamic compression screw and required accessories, intended to provide adequate initial compression and adequate compression over an extended period of time when used in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of small bones. For example, if there is bone resorption, then the product will axially contract for continued compression.

The OsteoCoil GT implants are comprised of an implantable, cannulated rod with a threaded region at the distal end. The unthreaded portion of the rod contains a helical cut or dynamic compression feature which allows axial elongation. A thin-walled tube with a head at the proximal end is seated around the cannulated rod and attached at the head end. There is a torque bearing mechanism at the distal interface of the sleeve and internal rod, which allows torque to be transmitted without loading the compression element. The cannulation allows for insertion over a guidewire. The head engages with a proximal end of a first bone segment, and the threaded region engages with a second bone segment. The head also includes a drive feature for insertion. The system is comprised of sterile implants for single use only. Instruments are provided non-sterile and may be reprocessed.

VI. Intended Use

The OsteoCoil™ GT Active Compression System is intended for use in bone fragment stabilization and boney fusion.

VII. Indications for Use

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

VIII. Comparison of Technological Characteristics with Predicate Device

The Subject and Predicate devices in this submission are almost identical, with differences limited to minor design characteristics.

Table 1: General Technological Characteristics Comparison

Product Features	**Subject Device** **Conventus' OsteoCoil™ GT Active Compression System (K260106)**	**Predicate Device** **Conventus' OsteoCoil™ Nitinol Compression System (K233567)**
Classification	Class II	SAME
Product Code	HWC	SAME
Regulation Number	§888.3040	SAME
Regulation Name	Smooth or threaded metallic bone fixation fastener	SAME
Intended Use	The OsteoCoil™ GT Active Compression System is intended for use in bone fragment stabilization and boney fusion.	SAME
Indications for Use	The OsteoCoil™ GT Active Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, & fracture	SAME

Table 1: General Technological Characteristics Comparison

Product Features	**Subject Device** **Conventus' OsteoCoil™ GT Active Compression System (K260106)**	**Predicate Device** **Conventus' OsteoCoil™ Nitinol Compression System (K233567)**
	fixation for small bones for wrist, hand, and foot.	
Materials	Nitinol ASTM	SAME
Environment of Use	Hospital	SAME
Provided Sterile	Implants – Yes Instruments – No	SAME
Principle of Operation	The OsteoCoil™ GT Active Compression System supports the fracture site in the same way traditional bone screws do while taking advantage of the patient anatomy and bone healing occurring at the injury site. The proprietary compressive technology of the implant causes an opposing compression force between the implant head and threads. Typically, a bone screw provides an initial compression force which is lost as soon as there is bone length loss due to bone remodeling. The unique OsteoCoil implant results in a compression force applied across a bony fusion site even with loss of length throughout	The principle of operation is the same, except that the OsteoCoil Nitinol Compression System does not have the torque bearing mechanism in the Subject Device. Therefore, the transmission of torque is less efficient.

Table 1: General Technological Characteristics Comparison

Product Features	Subject Device Conventus' OsteoCoil™ GT Active Compression System (K260106)	Predicate Device Conventus' OsteoCoil™ Nitinol Compression System (K233567)
	bone resorption. The OsteoCoil GT system adds a torque bearing mechanism to the implant shaft, which is distal to the helical shaft and reduces the torsional load on the helical compression feature.	
User Profile	Healthcare Professional Only	SAME
Single Use	Implants – Yes Instruments – No	SAME
Sterilization	Gamma Irradiation	SAME
SAL	10^{-6}	SAME
Shelf-Life	7 years	SAME

IX. Performance Data

Bench Testing

No additional bench performance testing is included to support this Traditional 510(k). The OsteoCoil™ GT Active Compression System and its Predicate Device are significantly similar in design, materials, and manufacturing, and Finite Element Analysis was performed to further confirm expected performance of the device.

Reprocessing, Sterility, and Shelf-Life

No additional reprocessing, sterility, and shelf-life testing is required as processes are identical to those in K233567. Routine pyrogen testing will be conducted on representative samples from each product lot.

Biocompatibility

No additional biocompatibility testing is required as manufacturing materials and processes are identical to those in K233567.

Electrical Safety and Electromagnetic Compatibility (EMC)

There are no electrical components in the proposed device. All components are components of Nitinol and have not been evaluated for electromagnetic compatibility.

Performance Testing – Animal

This submission does not include animal testing.

Performance Testing – Clinical

This submission does not include clinical testing.

X. Conclusion

Base on the data and justifications presented in this submission, The OsteoCoilTM GT Active Compression System is considered substantial equivalent to the OsteoCoil Nitinol Compression System.