April 13, 2022

Orthopedic Designs North America, Inc.
Robin Wilson
Quality Manager
5912 Breckridge Parkway, Suite F
Tampa, Florida 33610

Re: K210146
Trade/Device Name: Cannulated Compression Device System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 12, 2021
Received: October 13, 2021

Dear Robin Wilson:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210146

Device Name
Cannulated Compression Device System

Indications for Use *(Describe)*
The Cannulated Compression Device System is indicated for fracture fixation of small and long bones. The system is not intended for spinal use.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Date of Preparation: April 12, 2022

Company Name / Contact:

Company: Orthopedic Designs North America, Inc. (ODI-NA)
5912 Breckenridge Parkway
Suite F
Tampa, FL 33610

Contact: Robin Wilson
Phone: (813) 443-4905
Fax: (888) 632-8047

Device Identification:

Proprietary Name:	Cannulated Compression Device System
Common Used Name:	Non-Spinal Metallic Bone Screw
Classification Name:	Screw, Fixation, Bone
Classification Reference:	21 CFR § 888.3040
Classification Panel:	87 – Orthopedic Devices
Device Product Code:	HWC
Proposed Regulatory Class:	Class II

Predicate Devices:

Primary: Stryker® Asnis® III Cannulated Screw System (K000080)

Additional: Synthes® (USA) 6.5 mm Cannulated Screw (K021932)
Synthes® (USA) 4.5 and 6.5 mm Headless Compression Screws (K080943)

Device Description:

The Cannulated Compression Device System is used to aid in the alignment and stabilization of bone fractures. The system consists of the following parts:

- A **cannulated compression device body** with distal threads for bone engagement and distal portals that allow passage of deployable integral anchors to achieve stabilization distally within the bone. The anchors may be retracted for removal of the device if and when it is necessary. The device will be provided in a pre-assembled condition with the deployable anchors and a distal end cap already installed. The device will be available in a variety of lengths.
- A **compression nut** will be provided separately in various configurations, including both threaded and non-threaded versions. The compression nut has a proximal head and internal threads. The proximal head engages the bone fragment. The internal threads allow engagement to the cannulated compression device body. As the compression nut is tightened onto the device body compression is achieved across the bone fragments. The rate of compression varies based on the proximal head configuration selected.

ODi-NA will manufacture the implants from implant grade titanium alloy (Ti-6AL-4V-ELI) per ASTM F136. The implants will be offered in both sterile (steam) and non-sterile packaging configurations and are intended for single-use.

Indications for Use:

The Cannulated Compression Device System is indicated for fracture fixation of small and long bones. The system is not intended for spinal use.

Substantial Equivalence Information:

Orthopedic Designs North America, Inc. believes the Cannulated Compression Device System is substantially equivalent to the products described herein with respect to indications for use, device design, materials, method of manufacture and method of sterilization. The following technological differences exist between the subject and predicate devices:

- The predicate devices obtain fixation through distal threads alone. The subject device, while having distal threads, offers integral, deployable and retractable anchors to enhance fixation.
- The predicate devices offer a singular head design for each system. The subject device offers multiple head designs which allow the surgeon to choose the appropriate head design for the operation being performed.

Performance Data:

The subject devices were evaluated for their torsional strength, driving torque, and pullout strength per Annex A1, Annex A2, and Annex A3 of ASTM F543-17. The subject devices were evaluated for their static and dynamic bend strength per Annex A1 and Annex A4 of ASTM F1264-16.

The compression features of the subject device were comparatively tested against a predicate device.
Pyrogen testing was performed in accordance with ANSI/AAMI ST72 and confirmed the implants meet the specified endotoxin limit of 20.0 USP Endotoxin Units per device using the *Limulus* amebocyte lysate (LAL) test.

Conclusion:

The totality of data collected through comprehensive performance testing has successfully demonstrated the Cannulated Compression Device System is substantially equivalent to the previously cleared predicate devices currently marketed for the same intended use.