December 16, 2020

GLW Medical Innovation
% Cheryl Wagoner
Consultant
Wagoner Consulting LLC
5215 Crosswinds Drive
Wilmington, North Carolina 28409

Re: K200291
Trade/Device Name: CREED™ Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 14, 2020
Received: December 16, 2020

Dear Cheryl Wagoner:

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 -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

Traditional 510(k) Premarket Notification
CREED™ Cannulated Screws

510(k) Summary for K200291
(as required by 21 CFR 807.92)

Date Prepared	November 30, 2020
Manufacturer	GLW, Inc.
Address	300 Sylvan Ave Englewood Cliffs, NJ 07632
Telephone	917-794-2583
Contact Person	Arundhati Radhakrishnan
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Telephone	201-268-3281
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Trade Name	CREED™ Cannulated Screws
Common Name	Screw, Fixation, Bone
Panel Code	Orthopaedics/87
Classification Name	Smooth Or Threaded Metallic Bone Fixation Fastener
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	HWC

Name of Primary Predicate Device	**510(k) #**	**Manufacturer**
OsteoBullet Compression Screw	K160304	Phalanx Innovations
Name of Additional Predicate Devices		
DARCO Headless Compression Screw	K080850	Wright Medical Technology Inc.
Biomet BioDrive Cannulated Screw System	K082874	Biomet
Inion Freedomscrew	K123672	Inion OY

Description	CREED™ Cannulated Screws consists of subject components that will be available in thread diameters ranging from Ø2.5mm to Ø7.4 mm and lengths ranging from 14-120mm. They are either headed or headless compression. All screws are self-drilling and self-tapping. The screws are offered in configurations that include a Titanium alloy Ti-6AL-4V ELI (ASTM F136) screw and a Titanium alloy Ti-6AL-4V ELI (ASTM F136) screw with an outer layer of Zeniva ZA-600 PEEK (ASTM F2026). A variety of instrumentation is offered as

	part of the kit to facilitate delivery of the screws. The screws are provided sterile via Gamma irradiation. -

Indications and Intended Use	*CREED™ Cannulated Screws are intended to maintain alignment and fixation of bone fractures, comminuted fractures in the presence of appropriate additional immobilization such as rigid fixation implants, cast or brace, non-unions, osteotomies, arthrodesis or bone grafts in the hand, foot, and ankle including distal tibia and fibula. These implants are not intended for spinal use.*

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device is substantially equivalent to the predicate devices. The Subject device is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics, and labeling. The Subject device is similar in size and thread form as the predicate(s). The Subject and predicate both contain Ti-alloy screws. The subject device differs from the predicate because it contains PEEK screws with a titanium alloy core, whereas the predicate system offers all PEEK screws or all titanium alloy screws (no mixing of materials in a single screw).

Performance Data	Performance data presented in the application included: Axial pullout strength testing, torque to failure testing and insertion torque testing (ASTM F543). Static and dynamic 3-point bending (ASTM F1264) were also presented in addition to interface bond testing/delamination testing. Torsional resistance testing was performed for characterization. Biocompatibility per ISO 10993 and FDA guidance including cytotoxicity, irritation, sensitization, and chemical characterization were also evaluated.

Conclusion	Based on the intended use, indications for use, technological characteristics, materials, and performance comparison to predicate devices, the Subject device has been shown to be substantially equivalent to legally marketed predicate devices.