May 11, 2021

Wright Medical
Michael Mullins
SR Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K203228
Trade/Device Name: DART-FIRE EDGE Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 9, 2021
Received: April 12, 2021

Dear Michael Mullins:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203228

Device Name
DART-FIRE EDGE Cannulated Screw System

Indications for Use *(Describe)*
The DART-FIRE EDGE Cannulated Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of foot and ankle bones appropriate for the size of the device. Screws are intended for single use only.

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

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the DART-FIRE EDGE Cannulated Screw System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	October 30, 2020
Contact Person:	Michael Mullins Regulatory Affairs Specialist Phone – (901) 867-4142 Fax – (901) 867-4190
(a)(2). Proprietary Name:	DART-FIRE EDGE Cannulated Screw System
Common Name:	Bone Screw
Classification Name and Regulation:	Smooth or threaded metallic bone fixation fastener, 21 CFR 888.3040 – Class II
Device Product Code, Device Panel:	HWC – Orthopedic
(a)(3). Predicate Device:	K082320: Wright Compression Screws (*primary*) K080850: DARCO Headless Compression Screw (*reference*) K183696: PERFORM Reverse (*reference*)

(a)(4). Device Description

The DART-FIRE EDGE Cannulated Screw System contains partially and fully threaded, cannulated screws offered in a variety of diameters and lengths. The screws are manufactured from titanium alloy (ASTM F136).

(a)(5). INTENDED USE

The DART-FIRE EDGE Cannulated Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of foot and ankle bones appropriate for the size of the device. Screws are intended for single use only.

(a)(6). Technological Characteristics Comparison

The DART-FIRE EDGE Screw System is a new screw system. Compared to the legally marketed primary predicate, the subject system has identical indications, similar design features, the same sterilization method, and similar performance characteristics.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Performance testing and analysis demonstrated substantial equivalence to the predicate device in insertion torque, removal torque, pull out, ultimate torque, yield torque strength per ASTM F543 and simulated MR Safety testing per ASTM F2182 (RF Heating/Image Artifact) and ASTM F2052 (Induced Force/Torques).

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.