May 7, 2021

Wright Medical
Jonathan Dimotta
Regulatory Affairs Specialist II
1023 Cherry Road
Memphis, Tennessee 38117

Re: K203832
Trade/Device Name: FuseForce™ Flex Dynamic Compression System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: March 30, 2021
Received: March 31, 2021

Dear Jonathan Dimotta:

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,

Vesa Vuniqi
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*

K203832

Device Name

FuseForce™ Flex Dynamic Compression System

Indications for Use *(Describe)*

The FuseForce™ Flex Dynamic Compression System is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

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) 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 FuseForce™ Flex Dynamic Compression System.

(a)(1) MANUFACTURER IDENTIFICATION

Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	May 3, 2021
Contact Person:	Jonathan DiMotta Regulatory Affairs Specialist Office: (901) 867-4121 Fax: (901) 867-4190

(a)(2) SUBJECT DEVICE INFORMATION

Proprietary Name:	FuseForce™ Flex Dynamic Compression System
Common Name:	Bone Staple
Classification Name & Reference:	21 CFR 888.3030 – Class II
Device Product Code & Panel:	JDR – Orthopedic

(a)(3) PREDICATE DEVICE INFORMATION

FuseForce™ Implant System	K124045
Memodyn Staple	K161587 (reference)

(a)(4) DEVICE DESCRIPTON

The FuseForce™ Flex Dynamic Compression System consists of bone staple implants with two-leg and four-leg configurations. The system features low-profile and wide bridges, as well as multiple leg lengths. The implants are manufactured from nickel-titanium alloy (ASTM F2063). The system is provided as a single-use sterile pack comprising of a bone staple implant and instruments for implantation. The implant is designed to provide compression to facilitate bone fusion.

(a)(5) INTENDED USE

The FuseForce™ Flex Dynamic Compression System is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

The indications for the subject devices are substantially equivalent to those cleared under K124045. The predicate devices are indicated for use in the foot and hand, while the subject devices are indicated for the foot and ankle. The word “ankle” was included in the indications to provide additional clarity to the end user. As the subject devices’ intended use are identical with the exception of use in the hand, the indications are substantially equivalent to the predicate system.

(a)(6) **TECHNOLOGICAL CHARACTERISTICS COMPARISON**

Compared to the legally marketed primary predicate, the subject FuseForce™ Flex Dynamic Compression System has a similar design, indications for use, and performance characteristics. The system features the same principles of operation for bone fixation and sterilization method as the predicate system. The subject and predicate are manufactured from the same nitinol material (ASTM F2063) and share similar features such as their wingless design and legs with teeth. The subject bone staples feature wider bridges while maintaining similar bridge and leg lengths as the predicate devices. The subject system adds sizes with longer bridges, longer leg lengths, and 4-leg staples when compared to the predicate to further accommodate varying patient anatomy.

(b)(1) **SUBSTANTIAL EQUIVALENCE – NON-CLINICAL EVIDENCE**

Performance testing and engineering analysis demonstrated substantial equivalence to the predicate device in the following:

- Static bending, bending fatigue, and pullout strength (per ASTM F564)
- Corrosion resistance (per ASTM F2129 and ASTM F3306)
- Bacterial endotoxin (per ANSI/AAMI ST72:2019)

(b)(2) **SUBSTANTIAL EQUIVALENCE – CLINICAL EVIDENCE**

N/A

(b)(3) **SUBSTANTIAL EQUIVALENCE – CONCLUSIONS**

The design and performance 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 are considered substantially equivalent to the predicate device.