March 13, 2019

Wright Medical Technology, Inc.
Antonio Ayala
Regulatory Affairs Specialist I
1023 Cherry Road
Memphis, Tennessee 38117

Re: K183026
Trade/Device Name: Wright Jones Fracture System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 8, 2019
Received: February 11, 2019

Dear Antonio Ayala:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K183026

Device Name
Wright Jones Fracture System

Indications for Use *(Describe)*
The Wright Jones Fracture System is indicated for fixation of bone fractures or for bone reconstruction of the 5th Metatarsal. Examples include:

- Fixation of malunions and nonunions
- Acute fractures
- Avulsion fractures
- Repetitive stress fractures
- Jones Fractures
- Malleolar Fractures
- Talus Fractures
- Greater Tuberosity Fractures

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 Wright Jones Fracture System.

(a)(1). Submitted By:

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date:

October 31, 2018

Contact Person:

Antonio Ayala
Regulatory Affairs Specialist I
Phone – (901) 290-5640
Fax – (901) 867-4190

(a)(2). Proprietary Name:

Wright Jones Fracture 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:

K140952: CHARLOTTE™ CAROLINA™ Jones Fracture System Screw
K053136: 5th Metatarsal Fracture Screw

(a)(4). Device Description

The Wright Jones Fracture System consists of partially threaded, solid screws offered in 4.5, 5.5, and 6.5 mm diameters and various lengths. The screws are manufactured from titanium alloy (ASTM F136).

(a)(5). INTENDED USE

The Wright Jones Fracture System is indicated for fixation of bone fractures or for bone reconstruction of the 5th Metatarsal. Examples include:

- Fixation of malunions and nonunions
- Acute fractures
- Avulsion fractures
- Repetitive stress fractures
- Jones Fractures
- Malleolar Fractures
- Talus Fractures
- Greater Tuberosity Fractures

(a)(6). Technological Characteristics Comparison

The Wright Jones Fracture System Screw and the legally marketed predicates have identical indications, similar design features, the same sterilization method, and similar performance characteristics. The modifications to the system include additional sizes, chamfered and headless screw options, and an updated driver interface.

(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, and yield torque strength.

(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.