January 8, 2021

Wright Medical Technology, Inc.
Anna Hinton
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K201259
Trade/Device Name: ORTHOLOC 2 Pilon Fracture Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 23, 2020
Received: November 25, 2020

Dear Anna Hinton:

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)*
K201259

Device Name
ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System

Indications for Use *(Describe)*

The ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System is indicated for complex intra- and extra-articular fractures, osteotomies, and non-unions of the distal tibia, and fracture fixation of the fibula in skeletally mature patients. This includes periarticular stabilization and fixation of fragments in fresh fractures.

ORTHOLOC™ 3Di Locking Screws are intended for use with Wright's ORTHOLOC 3Di Plating Systems of the same base material.

ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Wright's washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

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 ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System.

a)(1) MANUFACTURER IDENTIFICATION

Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	December 22, 2020
Contact Person:	Anna Hinton Regulatory Affairs Specialist Office: (901)451-6362

(a)(2) SUBJECT DEVICE INFORMATION

Proprietary Name:	ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System
Common Name:	Bone Plate
Classification Name & Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030 (primary) – Class II Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040 – Class II
Device Product Code & Panel:	HRS – Orthopedic HWC— Orthopedic

(a)(3) PREDICATE DEVICE INFORMATION

ORTHOLOC 3Di Ankle Fracture Plating System	K163044 (primary)
ORTHOLOC 3Di Small Bones Forefoot System	K163039 (additional)
DARCO Small Screw	K082320 (additional)
ORTHOLOC 2.0/2.4 Plate System	K090692 (additional)
ORTHOLOC 3Di Ankle Plating System, ORTHOLOC Bone Screw	K102429 (additional)
ORTHOLOC 3Di Hallux System	K120359 (additional)
NCB Plating System Distal Femur and Proximal Tibia	K192217 (additional)

(a)(4) **DEVICE DESCRIPTON**

The subject ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System is designed to facilitate fracture fixation of the fibula and tibia. The system achieves its intended effect through the use of the various titanium alloy (Type II Anodized) straight, anatomical, and contoured plates and both locking and non-locking screws.

(a)(5) **INTENDED USE**

The ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System is indicated for complex intra- and extra-articular fractures, osteotomies, and non-unions of the distal tibia, and fracture fixation of the fibula in skeletally mature patients. This includes periarticular stabilization and fixation of fragments in fresh fractures.

ORTHOLOC™ Locking Screws are intended for use with Wright's ORTHOLOC® 3Di Plating Systems of the same base material.

ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Wright's washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

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

The ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System is manufactured from identical materials (i.e Titanium Alloy) and has identical sterilization methods as the legally marketed predicate device. The subject plates of the system are available in straight, anatomical, and contoured plates in the left and right orientations designed to maintain an anatomical fit across the bone, similar to the predicate plates. In order to achieve the intended effect, the subject and predicate plates and screws are both used to provide stabilization and to facilitate bone fusion. The subject plates are technologically substantially equivalent in material, size and bending strength to the predicate plates. The subject screws only vary in length from the predicate screws and the subject washers are unchanged from the predicate washers.

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

The following evaluations were conducted to support the safety and efficacy of the ORTHOLOC™ 2 with 3Di Technology Pilon Fracture Plating System:

Comparative, mechanical tested to predicate devices demonstrated substantial equivalence.

- Plates were tested per ASTM F382:
    - Static Four-Point Bend
    - Fatigue Four-Point Bend
- Tests Performed per ASTM F2182 to establish compatibility with a Magnetic Resonance Environment:
    - RF Heating
    - Induced Forces
    - Induced Torques
    - Image Artifact

- Engineering Justification for Additional Screw Lengths: by dimensional comparison, the additional screw lengths are substantially equivalent to the predicate screws in ASTM F543

- Pyrogencity Analysis**:** Pyrogen testing was conducted using the bacterial endotoxins test (BET) also known as LAL according to *ANSI/AAMI ST72:2011, Bacterial endotoxins – Test methods, routine monitoring and alternatives to batch testing*.

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

N/A

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

The design characteristics of the subject device do not raise any new types of questions of safety or effectiveness and testing shows no new worst case. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.