May 14, 2019

Wright Medical Technology, Inc.
Alayne Melancon
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K190670
Trade/Device Name: ORTHOLOC 2 Lapidus with Rotation 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
Dated: March 11, 2019
Received: March 15, 2019

Dear Alayne Melancon:

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,

Assistant Director
THT6C2: Fracture Fixation and Stereotaxic Devices Team
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K190670

Device Name
ORTHOLOC™ 2 Lapidus with Rotation System

Indications for Use *(Describe)*
The ORTHOLOC™ 2 Lapidus with Rotation System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of bones of the feet and toes. Specific examples include: Arthrodesis of the first metatarsal-cuneiform joint (Lapidus Fusion).

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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Memphis, TN 38117
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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 Lapidus with Rotation System.

(a)(1) **MANUFACTURER IDENTIFICATION**

| | |
|---|---|
| **Submitted By:** | Wright Medical Technology, Inc.<br>1023 Cherry Road<br>Memphis, TN 38117 |
| **Date:** | May 13, 2019 |
| **Contact Person:** | Alayne Melancon<br>Regulatory Affairs Specialist<br>Office: (901)290-5986<br>Fax: (901)867-4190 |

(a)(2) **SUBJECT DEVICE INFORMATION**

| | |
|---|---|
| **Proprietary Name:** | ORTHOLOC™ 2 Lapidus with Rotation System |
| **Common Name:** | Bone Plate |
| **Classification Name & Reference:** | Single/multiple component metallic bone fixation appliances and accessories - 21 CFR 888.3030 – Class II |
| **Device Product Code & Panel:** | HRS – Orthopedic |

(a)(3) **PREDICATE DEVICE INFORMATION**

| | |
|---|---|
| ORTHOLOC™ 3Di Hallux System | K120359 |

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

The ORTHOLOC™ 2 Lapidus with Rotation System is designed to facilitate arthrodesis of the first metatarsal-cuneiform joint, or Lapidus fusion. The system achieves its intended effect through the use of plates of various designs and both locking and non-locking screw configurations.

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

The ORTHOLOC™ 2 Lapidus with Rotation System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of bones of the feet and toes. Specific examples include: Arthrodesis of the first metatarsal-cuneiform joint (Lapidus Fusion).

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

The ORTHOLOC™ 2 Lapidus with Rotation 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 both large and standard, left and right orientations, and are designed with plantar steps to maintain an anatomical fit across the joint for varying amounts of correction.

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

The following evaluations were conducted to support the safety and efficacy of the ORTHOLOC™ 2 Lapidus with Rotation System

- Static Four-Point Bend Testing per ASTM F382
- Pyrogencity Analysis per ANSI/AAMI ST72:2011

(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.