DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 5, 2014

Wright Medical Technology, Inc.
Ms. Jeanine Redden
Director, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

Re: K143025
Trade/Device Name: Total Compression Plating (TCP) 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: October 20, 2014
Received: October 21, 2014

Dear Ms. Redden:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143025

Device Name
TOTAL COMPRESSION PLATING (TCP) SYSTEM

Indications for Use *(Describe)*
The TC Plating System is intended for essentially non-load bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe and pelvis.

Specific examples of use in the foot include:
Mid / Flatfoot Fusions
• LisFranc Arthrodesis and/or Stabilization
• 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
• Intercuneiform Fusions
• Navicular-Cuneiform (NC) Fusion
• Talo-Navicular (TN) Fusion
• Calcaneo-Cuboid (CC) Fusion
• Medial Column Fusion
First metatarsal osteotomies for hallux valgus correction including:
• Opening base wedge osteotomy
• Closing base wedge osteotomy
• Crescentic osteotomy
• Proximal Chevron osteotomy
• Distal Chevron osteotomy (Austin)
First metatarsal fracture fixation
Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
Arthrodesis of the first metatarsophalangeal joint (MTP) including:
• Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
• Revision MTP Fusion
• Revision of failed first MTP Arthroplasty implant

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

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 TOTAL COMPRESSION PLATING SYSTEM.

1. Submitted By: Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: November 24, 2014

Contact Person: Jeanine Redden
Director, Regulatory Affairs
Phone: 901.867.4255
Fax: 901.867.4190

2. Proprietary Name: TOTAL COMPRESSION PLATING SYSTEM

Common Name: Plate, Fixation, Bone

Classification Name and Reference: 21 CFR 888.3030- Class II

Device Product Code, Device Panel: HRS - Orthopedic

3. Predicate Device: K094037 TC Plating System
K121651 ORTHOLOC™ 3Di Midfoot/Flatfoot System
K120359 ORTHOLOC™ 3Di Hallux System

4. Device Description

The TOTAL COMPRESSION PLATING SYSTEM is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation of small bone fragments. Most of the plates are scalloped in shape to allow easier bending to fit the contour of the bone. There are also non-scalloped plates to provide greater strength. The plates include straight, right, and left configurations.

5. Intended Use

The TC Plating System is intended for essentially non-load bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe and pelvis.

Specific examples of use in the foot include:
Mid / Flatfoot Fusions

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic osteotomy
- Proximal Chevron osteotomy
- Distal Chevron osteotomy (Austin)

First metatarsal fracture fixation
Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

6. Technological Characteristics Comparison

The TOTAL COMPRESSION PLATING SYSTEM compared to the legally marketed predicate device has the same indications and is composed of the same material as the predicate screws and plates. The geometry of the subject screws and plates differ from the predicate screws and plates. Mechanical testing and engineering analysis ensure that the subject devices are substantially equivalent to the predicate devices.

7. Substantial Equivalence- Non-Clinical Evidence

Mechanical testing and engineering analysis has shown that the performance of the subject plating system is statistically equivalent or greater than the predicate plating system. Specifically cantilever bend testing was performed and used to assess ultimate load, yielding bending moment, bending stiffness, and maximum deflection according to ASTM F2193.

8. Substantial Equivalence- Clinical Evidence

N/A

9. Substantial Equivalence- Conclusions

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. Mechanical testing and engineering analysis has shown that the performance of the subject plating system is statistically equivalent or greater than the predicate plating system. 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.