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JUL 09 2014

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 CHARLOTTE™ MTP Bone Fusion Plate System.

1. **Submitted By:** Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Date: June 10, 2014

Contact Person: Leslie Fitch
Senior Regulatory Affairs Specialist
Office (901) 867-4120
Fax (901) 867-4190

2. **Proprietary Name:** CHARLOTTE™ MTP Bone Fusion Plate System

Common Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories

Classification Name and Reference: 21 CFR 888.3030- Class II

Device Product Code, Device Panel: HRS - Orthopedic

3. **Predicate Device:** K042205 Bone Fusion Plate

4. **Device Description**

The CHARLOTTE™ MTP Bone Fusion Plate System consists of plates in left and right configurations and screws. All screws and plates are manufactured from stainless steel (ASTM F138).

The design features and function of the screws included in the CHARLOTTE™ MTP Bone Fusion Plate System are substantially equivalent to the design features previously cleared under the Bone Fusion Plate (renamed and from here on referred to as: CHARLOTTE™ MTP Bone Fusion Plate System). The system includes 2.7mm and 3.7mm screws in lengths from 8mm to 24mm.

5. Intended Use

The CHARLOTTE™ MTP Bone Fusion Plate System is intended to help increase the rate of bony union, and to maintain the position of the toe during fusion. Once the joint has fused, the plate is secondary in the transmission of gait forces.

Indications for Use:
- Fractures, osteotomies or arthrodesis of the first metatarsal-phalangeal joint
- Deformity due to hallux valgus
- Deformity due to arthritis in the first metatarsal-phalangeal joint
- Loss of motion- hallux rigidus
- Pain associated with osteoarthritis or rheumatoid arthritis in the first metatarsal-phalangeal joint
- Revision procedures where other treatments or devices have failed; and
- Chronic instability in the first metatarsal-phalangeal joint

6. Technological Characteristics Comparison

The CHARLOTTE™ MTP Bone Fusion Plate System and the legally marketed predicate CHARLOTTE™ MTP Bone Fusion Plate System Screw have identical indications, have the same overall features, and are identical in material. The only difference is the driver interface change in the head of the screw and the addition of parts provided sterile. There have been no changes to the plates and the compatibility is unchanged from the predicate.

7. Substantial Equivalence- Non-Clinical Evidence

Mechanical testing, including Torsional Yield Strength per ASTM F543-02, has shown that the performance of the subject screw is statistically equivalent or greater than the predicate screw.

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. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 9, 2014

Wright Medical Technology, Inc.
Dr. Leslie Fitch
Senior Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K141417
Trade/Device Name: CHARLOTTE™ MTP Bone Fusion Plate 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: June 10, 2014
Received: June 16, 2014

Dear Dr. Fitch:

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" (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 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,

Lori A. Wiggins

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)*
K141417

Device Name
CHARLOTTE™ MTP Bone Fusion Plate System

Indications for Use *(Describe)*
The CHARLOTTE™ MTP Bone Fusion Plate System is intended to help increase the rate of bony union, and to maintain the position of the toe during fusion. Once the joint has fused, the plate is secondary in the transmission of gait forces.

Indications for Use:
- Fractures, osteotomies or arthrodesis of the first metatarsal-phalangeal joint
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- Loss of motion- hallux rigidus
- Pain associated with osteoarthritis or rheumatoid arthritis in the first metatarsal-phalangeal joint
- Revision procedures where other treatments or devices have failed; and
- Chronic instability in the first metatarsal-phalangeal joint

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)*

Elizabeth L. Frank -S

Division of Orthopedic Devices

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