



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

Wright Medical Technology, Incorporated
Mr. Michael Mullins
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

September 4, 2015

Re: K151838

Trade/Device Name: PRO-TOE Hammertoe Fixation System – C2 Implant Line Addition
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 30, 2015
Received: July 6, 2015

Dear Mr. Mullins:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*

K151838

Device Name

PRO-TOE Hammertoe Fixation System - C2 Implant Line Addition

Indications for Use *(Describe)*

The PRO-TOE® Hammertoe Fixation Systems are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PRO-TOE® Hammertoe Fixation Systems, with the exception of the PRO-TOE® X-FLEX, can be used with Implantable K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

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 PRO-TOE® Hammertoe Fixation System – C2 Line Addition.

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

Date: June 30, 2015

Contact Person: Michael Mullins
Regulatory Affairs Specialist
Office: (901) 867-4142
Fax: (901) 867-4190
2. **Proprietary Name:** PRO-TOE® Hammertoe Fixation System

Common Name: Smooth or threaded metallic bone fixation fastener

Classification Name - Reference: 21 CFR 888.3040- Class II

Product Code - Device Panel: HWC - Orthopedic
3. **Predicate Device:** K132895 - WMT Implantable K-Wire
K140148 - PRO-TOE® Hammertoe Fixation System
4. **Device Description**
The PRO-TOE® Hammertoe Fixation System is composed of implants and instruments intended for use in the fixation or reconstruction of the lesser toes. The implants within the PRO-TOE® Hammertoe System have proximal & distal fixation features and are offered in multiple sizes. The implants are manufactured from stainless steel and titanium alloy.

5. Intended Use and Indications for Use

The PRO-TOE® Hammertoe Fixation Systems are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PRO-TOE® Hammertoe Fixation Systems, with the exception of the PRO-TOE® X-Flex, can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

6. Technological Characteristics Comparison

The PRO-TOE® Hammertoe Fixation System and the legally marketed predicate devices have similar indications and dimensions and have similar geometry and identical material. The purpose of this submission is to add additional sizes of the PRO-TOE® C2 implants to the PRO-TOE® Hammertoe System as well as update design of the VO Cannulated and C2 implants.

7. Substantial Equivalence- Non-Clinical Evidence

Analysis related to pullout and static bend testing has shown that the subject implants do not present a new worst case.

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.