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JUL 2 3 2010

WRIGHT.

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™ VO Hammertoe Implant System.

A.1. Submitted By: Wright Medical Technology, Inc.
5677 Airline Rd
Arlington, TN 38002

Date: April 23, 2010

Contact Person: Kelsey Lee
Regulatory Affairs Specialist I
(901) 290-5909

A.2. Proprietary Name: **PRO-TOE™ VO Hammertoe Implant System**

Common Name: Intramedullary Bone Fastener

Device Classification Regulation: 21 CFR 888.3040--Class II

Device Product Code & Panel: HWC: Screw, Fixation, Bone
87 Orthopedics

A.3. Predicate Device: newdeal® K-Wire (K022599)

A.4. Device Description

The PRO-TOE™ VO Hammertoe Implant System will be offered in two sizes and two different blade angles. The implants will be manufactured from stainless steel.

The design features of the PRO-TOE™ VO Hammertoe Implant System are substantially equivalent to the design features of other devices previously cleared for market.

A.5. Intended Use

The PRO-TOE™ VO Hamemrtoe Implant System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

The indications are similar to the legally marketed predicate device. Wright Medical Technology, Inc. has chosen to include specific types of reconstruction to focus on the market in which the subject device is being promoted.

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A.6. Technological Characteristics Comparison

The subject PRO-TOE™ VO Hammertoe Implants and the legally marketed predicate newdeal® K-wires have similar indications and are both manufactured from stainless steel.

The PRO-TOE™ VO Hammertoe Implants differ from the legally marketed predicate newdeal® K-wires in size offerings and fixation design characteristics.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through cantilever bend testing. The results of the test show that the subject PRO-TOE™ VO Hammertoe implants can be expected to perform at least as well as the legally marketed predicate newdeal® K-wires.

The safety and effectiveness of the PRO-TOE™ VO Hammertoe Implant System is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within the Premarket Notification.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

Substantial equivalence is shown through a cantilever bend test. The materials and indications are similar and the subject and predicate differ in fixation design characteristics and diameters, but no new types of safety and effectiveness questions can be expected. From the evidence given in the Premarket Notification, the subject devices can be expected to perform at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Wright Medical Technologies, Inc.
% Ms. Kelsey Lee
5677 Airline Road
Arlington, TN 38002

JUL 2 3 2010

Re: K101165
Trade/Device Name: PRO-TOE VO Hammertoe Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 2, 2010
Received: July 6, 2010

Dear Ms. Lee:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101165

Device Name: PRO-TOE™ VO Hammertoe Implant System

Indications For Use:

The PRO-TOE™ VO Hammertoe Implant system is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101165