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

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

June 30, 2017

Re: K170249
Trade/Device Name: GRAVITY™ Syndesmosis LP
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN, HRS
Dated: May 23, 2017
Received: May 24, 2017

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" (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,

Mark N. Melkerson -S

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)*
K170249

Device Name
GRAVITY™ Syndesmosis LP

Indications for Use *(Describe)*
The GRAVITY™ Syndesmosis LP System is intended to provide fixation during the healing process following trauma to the Ankle Syndesmosis (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for ankle fractures such as Weber B and C.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 GRAVITY Syndesmosis LP.

(a)(1). Submitted By:

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: June 27, 2017

Contact Person:

Michael Mullins
Regulatory Affairs Specialist
Fax – (901) 867-4190

(a)(2). Proprietary Name: GRAVITY™ Syndesmosis LP

Common Name:

Washer, Bolt Nut
Plate, Fixation, Bone

Classification Name and Reference: 21 CFR 888.3030 – Class II

Device Product Code, Device Panel:

HTN – Orthopedic
HRS – Orthopedic

(a)(3). Predicate Device:

Primary: K043248-Arthrex TightRope™
Reference: K083070-Biomet ToggleLoc™
Reference: K163044-ORTHOLOC 3Di Ankle Fracture Plating System
Reference: K113871-PRODENSE (ABS instruments)

(a)(4). Device Description

The subject GRAVITY™ Syndesmosis LP is a sterile, single-use, device intended to stabilize syndesmotic trauma of the ankle. The subject system consists of UHMWPE suture tensioned between two titanium alloy buttons.

(a)(5). INTENDED USE

The GRAVITY™ Syndesmosis LP System is intended to provide fixation during the healing process following trauma to the Ankle Syndesmosis (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for ankle fractures such as Weber B and C.

(a)(6). Technological Characteristics Comparison

The subject GRAVITY™ Syndesmosis LP is technologically substantially equivalent to predicate devices in material, component design (i.e. suture, buttons), surgical technique, and construct design.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Performance testing and analysis demonstrated substantial equivalence in side by side construct static and dynamic tensile testing. Bacterial endotoxin levels on the final finished form of the device were evaluated using LAL pyrogen testing.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system 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 device.