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

April 29, 2015

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

Re: K150520
Trade/Device Name: DARCO® Locking Bone 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: March 31, 2015
Received: April 3, 2015

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,

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 below.

510(k) Number *(if known)*
K150520

Device Name
DARCO Locking Bone Plating System

Indications for Use *(Describe)*
The DARCO® Locking Bone Plate System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the feet, ankles and toes. The system can be used in both adult and pediatric patients.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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 DARCO® Locking Bone Plate System.

(a)1.	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	February 26, 2015
	Contact Person:	Jeanine Redden Director, Regulatory Affairs Office (901) 867-4522 Fax (901) 867-4190
(a)2.	**Proprietary Name:**	DARCO® Locking Bone Plate System
	Common Name:	Single/Multiple component metallic Bone Fixation Plate
	Classification Name and Reference:	Single/Multiple component metallic Bone Fixation Plate
	Device Product Code, Device Panel:	HRS - Orthopedic
(a)3.	**Predicate Device**:	K061808 DARCO® Locking Bone Plate System

(a)(4). Device Description

The DARCO® Locking Bone Plate System is designed with rhombus (parallelogram) plates of biocompatible titanium. The plates use either 2.7mm or 3.5mm screws which intersect each other in pairs. The drill holes of the plates are aligned to assure the screws do not touch. The plates vary essentially through different curvatures, material strengths, lengths, number of plate holes and through different grades or bridge widths.

(a)(5). Intended Use

The DARCO® Locking Bone Plate System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the feet, ankles and toes. The system can be used in both adult and pediatric patients.

(a)(6). Technological Characteristics Comparison

The DARCO® Locking Bone Plate System is substantially equivalent to the predicates. Two additional locking bone plates are being added to the subject DARCO® Locking Bone Plate System: the TOM Plate (Step) and the Rahmanzadeh plate (General). Both of these plates have identical indications, identical material composition and similar design features compared to other plates of the DARCO® System.

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

The DARCO® Locking Bone Plate System is substantially equivalent to the predicates. Analysis has shown that the performance of the subject bone locking plate system is not a worse case construct of the predicate DARCO® Locking Bone Plate family which is equivalent to the original predicate Normed Titanium Osteotomy Plating system design. The safety and effectiveness of the DARCO® Locking Plate System is adequately supported by the testing rationales, substantial equivalence information, and comparison of design characteristics provided within this premarket notification.

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

N/A

(b)(3). Substantial Equivalence- Conclusions

The design characteristics of the subject devices do not raise affect the safety or effectiveness of the system. From the evidence submitted in this 510(k), the subject devices can be expected to perform substantially equivalent to the predicate system.