Wright Medical Technology, Inc.
Val Myles
Senior Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K171852
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: August 29, 2017
Received: August 30, 2017

September 21, 2017

Dear Ms. Myles:

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 (DICE) 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 (DICE) 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
### Indications for Use

**510(k) Number (if known)**  
K171852

**Device Name**  
DARCO™ Locking Bone Plate 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)**

- [x] Prescription Use (Part 21 CFR 801 Subpart D)  
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*
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: June 16, 2017

Contact Person: Val Myles
Regulatory Affairs Specialist
Office (901) 290-5162
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: 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories

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 comprised of a variety of titanium plates and screws designed for internal fixation of bone fragments. The plates are designed with rhombus (parallelogram) plates with an assortment of width, lengths, and configurations to address varying patient anatomy. The system includes locking and non-locking 2.7 mm and 3.5 mm diameter screws of various lengths.

(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™ System 3.5 mm locking screw head has been modified and is substantially equivalent to the predicate. The subject device has identical indications, identical material and similar design features compared to screws in the DARCO® System.

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

Testing and rationale related to pullout strength, insertion, removal, ultimate/yield, and screw head locking torques were performed to demonstrate substantial equivalence. 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 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 devices.