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

August 15, 2016

Miami Device Solutions, LLC
Ms. Michelle Montesino
Regulatory Affairs Associate
7620 North West 25th Street, Unit 3
Miami, Florida 33122

Re: K161292
Trade/Device Name: Distal Radius Plating 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, HWC
Dated: July 7, 2016
Received: July 8, 2016

Dear Ms. Montesino:

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 Parts 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,

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)* K161292

Device Name
Distal Radius Plating System

Indications for Use *(Describe)*
The MDS Distal Radius Plating System is intended for internal fixation of fractures of the distal radius.

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.

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

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510(k) SUMMARY

Submitter Name:	Miami Device Solutions, LLC
Submitter Address:	7620 NW 25th Street, Unit 3; Miami, FL 33122
Contact Person:	Michelle Montesino Phone: (786) 422-1400 Ext. 106 Fax: (786) 422-1401
Date of Submission:	August 5, 2016
Manufacturer Name:	Miami Device Solutions, LLC
Manufacturer Address:	7620 NW 25th Street, Unit 3; Miami, FL 33122
Registration Number:	3009222247
Contact Name:	Markku Biedermann
Title:	President
Device Trade Name:	Distal Radius Plating System
Device Common Name:	Distal Radius Plating System
Classification Names:	Plate, fixation, bone; and screw, fixation, bone
Classification Code:	HRS; and HWC – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR section 888.3030; and 888.3040
Predicate Devices:	Synthes Locking Distal Radius Plate System – K012114 Variax Distal Radius Plating System – K141430 Proximal Humerus Plating System – K141493
Reference Devices:	Paragon 28, Inc.; The Monster Screw System: Instrument Reprocessing Instructions for Reusable Instruments – K151418

Device Description:
The Distal Radius Plating System is an internal fixation system to be used for the treatment of distal radius fractures. The system consists of plates, screws, and locking caps. The Distal Radius Plates are bilateral and available in two different models; standard or with a multi-directional oblong hole (MDOH) feature. Each model comes in two sizes, 5 hole and 6 hole. The Distal Radius Plating System Screws are 2.7mm in diameter and available in various lengths.

The MDS device is single-use ONLY.

Materials: Ti-6Al-4V ELI alloy conforming to ASTM F136.

Intended Use:
The MDS Distal Radius Plating System is intended for internal fixation of fractures of the distal radius.

Summary of Technologies:
The Distal Radius Plating System has the same intended use, similar performance characteristics, and is similar in design and materials to the Synthes (K012114) and Stryker (K141430) predicate devices listed above; with the exception of the Miami Device Solutions predicate (K141493) which is indicated for the proximal humerus. The Miami Device Solutions Proximal Humerus Plating System (K141493) is considered a predicate because it utilizes the same locking technology as the subject device. Additionally, the subject device provides the option of a multi-directional oblong hole (MDOH) that the listed predicates do not.

Performance Data:

Non-Clinical Performance and Conclusions:

The results of non-clinical (laboratory/performance) testing demonstrate that the subject and predicate devices have similar performance properties. Substantial equivalence was demonstrated in the performance testing section of the submission by comparing the design and testing according to ASTM F382-99, Standard Test Method for Metallic Medical Bone Plates and ASTM F543-07, Standard Specification and Test Method for Metallic Bone Screws, which show that the Distal Radius Plating System performs as well as the predicate devices. Comparison of the design, intended use, and testing demonstrate that the Distal Radius Plating System performs as well as the predicate devices and should thereby be considered substantially equivalent.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion
The Miami Device Solutions Distal Radius Plating System is substantially equivalent to the predicate devices.