



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

October 21, 2016

Re: K162635

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: September 20, 2016

Received: September 21, 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

Indications for Use

510(k) Number (if known)

K162635 (Page 1 of 1)

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.

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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
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Date of Submission: September 20, 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: Miami Device Solutions Distal Radius Plating System – K161292

Device Description:

This special 510(k) submission is intended to add the following device instruments and caddy as accessories to the Miami Device Solutions Distal Radius Plating System which was cleared in K161292:

1. Polyaxial Drill Guide
2. Polyaxial Drill Guide Sleeve for K-Wire
3. Polyaxial Drill Guide Caddy

The polyaxial drill guide caddy holds polyaxial drill guides and polyaxial drill guide sleeves for K-wires. The polyaxial drill guide and the polyaxial drill guide sleeve for K-wire helps the user during drill and K-wire insertion. 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.

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

Intended Use:

The addition of the polyaxial drill guide caddy, polyaxial drill guides, and polyaxial drill guide sleeves for K-wire does not alter the intended use of the predicate system as cleared in K161292 Distal Radius Plating System. The indications for use for the subject device are provided below.

Indications for Use

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

Summary of Technologies:

The proposed device is substantially equivalent in intended use, materials, and performance characteristics to the predicate device. The addition of the following instruments as accessories to the plating system does not alter the technology.

Performance Data:

Non-Clinical Performance and Conclusions:

The additional instruments and caddy were shown to be compatible with applicable implants and instruments. Verification testing showed that the system is biocompatible and can be cleaned and sterilized.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion

The Miami Device Solutions Distal Radius Plating System and the addition polyaxial drill guides, polyaxial drill guide sleeves for K-wire, and the polyaxial drill guide caddy is substantially equivalent to the predicate device.