December 10, 2018

Miami Device Solutions, LLC
Michelle Montesino
Regulatory Affairs Specialist
7620 NW 25th Street, Unit 3 & 4
Miami, Florida 33122

Re: K182810
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: November 16, 2018
Received: November 19, 2018

Dear Michelle 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182810

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 & 4; Miami, FL 33122

Contact Person: Michelle Montesino
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Date of Submission: October 2, 2018

Manufacturer Name: Miami Device Solutions, LLC

Manufacturer Address: 7620 NW 25th Street, Unit 3 & 4; 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:

K161292, K162635,	Primary	Miami Device Solutions Distal Radius Plating System
K071092,	Secondary	Stryker Asnis Micro Cannulated Screw
K133246,	Secondary	Zimmer Distal Radius Plating System

Reference Devices:

K041461	Kinetikos Medical Inc. Distal Volar Radius Plate System (Viper Plate)

K151418	The Monster Screw System: Instrument Reprocessing Instructions for Reusable Instruments

Device Description:
This special 510(k) submission is intended to add new plate designs, screw diameter options and lengths, pegs, and accompanying instrumentation to the Miami Device Solutions Distal Radius Plating System cleared through K161292/K162635.

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, pegs, and locking caps. The Distal Radius Plates are available in bilateral and side-specific designs to accommodate different anatomies and fracture patterns. The addition of new devices through this special 510(k) provides the user with more options for fixation.

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

Intended Use:
The addition of devices through this special 510(k) does not alter the intended use of the predicate system as cleared in K161292/K162635, 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 devices to the plating system through this special 510(k) does not alter the fundamental technology and operating principles of the Distal Radius Plating System.

Performance Data:

Non-Clinical Performance and Conclusions:

The results of non-clinical (laboratory/performance) testing as well as engineering analysis for subject devices demonstrate that the device is as safe and as effective as the predicates. Substantial equivalence is demonstrated in the performance testing section of the submission by comparing subject and predicate designs, as well as testing according to ASTM F543-07, Standard Specification and Test Method for Metallic Bone Screws. Comparison of the design, intended use, and testing support substantial equivalence of the subject device to the predicate.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion
The Miami Device Solutions Distal Radius Plating System with the addition of devices through this special 510(k) is substantially equivalent to the predicate device.