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

December 8, 2017

Re: K172786
Trade/Device Name: MDS 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 14, 2017
Received: September 15, 2017

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. 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.

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.

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,

Katherine D. Kavlock -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)*

K172786

Device Name
MDS Plating System

Indications for Use *(Describe)*

The MDS Plating System is intended for internal fixation of fractures of various bones such as the clavicle, olecranon, humerus, radius, ulna, distal tibia, and fibula and for use in fixation of periprosthetic fractures. The system can be used with commercially available cerclage cable of material compatible with system implants including titanium alloy and cobalt chromium.

The Low Profile Head Screw is used independently and is intended for internal fixation of fractures of the clavicle, olecranon, humerus, radius, ulna, distal tibia, fibula as well as foot and ankle.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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
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Date of Submission: 9/14/2017

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: MDS Plating System

Device Common Name: Primary: Plate, Fixation, Bone
Secondary: Screw, Fixation, Bone

Classification Names: Primary: Plate, fixation, bone
Secondary: Screw, fixation, bone

Classification Code: Primary: HRS – Class II
Secondary: HWC – Class II

Classification Panel: Orthopedic

Regulation Number: Primary: 21 CFR section 888.3030 – Single/multiple component metallic bone fixation appliances and accessories

Secondary: 21 CFR section 888.3040 – Smooth or threaded metallic bone fixation fastener

Predicate Device:

Primary	K143394	Acumed Small Fragment Base Set
Secondary	K161292/ K162635	Miami Device Solutions Distal Radius Plating System
Secondary	K162898	Miami Device Solutions Olecranon

		Plating System
Secondary	K141493	Miami Device Solutions Proximal Humerus Plating System
Secondary	K992891	Synthes Cerclage Positioning Pin
Secondary	K132502, K140769	Variax 2 System Bone Screws

Reference Devices: Paragon 28, Inc.; The Monster Screw System: Instrument Reprocessing Instructions for Reusable Instruments – K151418

Device Description:
The MDS Plating System is an internal fixation system intended for internal fixation of fractures of various bones. The system consists of the following single-use implants:

- Straight (broad and narrow) and pre-contoured plates available in a variety of sizes
- Screws of various lengths and diameters, some of which are identified in previously cleared premarket notifications (K141493, K161292/K162635, and K162898).
- Locking Caps of various diameters identified in previously cleared premarket notifications (K141493, K161292/K162635, and K162898).
- Low Profile Head Screws
- Threaded cerclage buttons of various diameters used in conjunction with MDS plates to augment fracture stabilization.

Additionally, the system includes single use and reusable instruments.

Materials: Titanium alloy and Stainless Steel.

Intended Use:
The MDS Plating System is intended for internal fixation of fractures of various bones such as the clavicle, olecranon, humerus, radius, ulna, distal tibia, and fibula and for use in fixation of periprosthetic fractures. The system can be used with commercially available cerclage cable of material compatible with system implants including titanium alloy and cobalt chromium.

The Low Profile Head Screw is used independently and is intended for internal fixation of fractures of the clavicle, olecranon, humerus, radius, ulna, distal tibia, fibula as well as foot and ankle.

Substantial Equivalence Statement:
Documentation is provided which demonstrates that the MDS Plating System is equivalent to its predicate devices in terms of material, design, indications for use, and performance characteristics.

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 predicated designs, as well as testing according to ASTMF382-99, Standard Test Method for Metallic Medical Bone Plates and ASTM F543-07, Standard Specification and Test Method for Metallic Bone Screws. Comparison of the design, intended use, and testing demonstrate that the MDS 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 MDS Plating System is substantially equivalent to the predicate devices.