



Skeletal Dynamics, LLC
Ana Escagedo
President
7300 North Kendall Drive, Suite 400
Miami, Florida 33156

October 10, 2018

Re: K182492

Trade/Device Name: Geminus Volar Distal Radius 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: September 7, 2018
Received: September 11, 2018

Dear Ana Escagedo:

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,

Jesse Muir -S

2018.10.10 12:54:36 -04'00'

For:

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)

K182492

Device Name

Geminus Volar Distal Radius Plate System

Indications for Use (Describe)

The Skeletal Dynamics Geminus Volar Distal Radius Plate System is intended for fixation of fractures and osteotomies 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

Skeletal Dynamics Geminus Volar Distal Radius Plate System

August 21, 2018

Submitter:

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Tel: (305) 596-7585
Fax: (305) 596-7591
Contact: Ana M. Escagedo, President
Email: aescagedo@skeletaldynamics.com

Establishment Registration Number: 3006742481

Name and Classification:

Name	Geminus Volar Distal Radius Plate System
Common Name	Plate, Fixation, Bone
Classification	21 CFR §888.3030
Product Code	HRS
Class	Class II

Predicate Devices:

Primary: Geminus Volar Distal Radius Plate System (K111620)
Synthes LCP Diaphyseal-metaphyseal (dia-meta) Volar Distal Radius Plate (K070946)

Description of the Device:

The Skeletal Dynamics Geminus Volar Distal Radius Plate System contains bone plates for the repair of distal volar radial fractures. Included in the set are titanium bone screws, fixation pegs, fragment plates, and specialized instrumentation. Also included are a Hook Plate Extension to buttress a volar marginal fragment, and cannulated cobalt chrome polyaxial locking screws for trajectories different than those of the fixed angled bone plates.

The Geminus Volar Distal Radius Plates are available in various sizes and are made of medical grade titanium alloy. Cortical screws affix the plate to the diaphysis and fixed angle pegs are used for distal bone fragments. The system is provided non- sterile and is sterilized in the user facility.

The Geminus Volar Distal Radius Plate System is comprised of:

- Titanium alloy plates, washers and screws
- CoCr Cannulated Polyaxial Locking Screw (PLS)
- Stainless steel K-wires (for provisional fixation; not for implantation)
- System specific instrumentation

Indications for Use:

The Geminus Volar Distal Radius Plate System is intended for fixation of fractures and osteotomies of the distal radius.

Technological Characteristics:

The substantial equivalence of the Geminus Volar Distal Radius Plate System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging, and does not present any new issues of safety or effectiveness.

Performance Testing:

Engineering analysis and testing demonstrated that the Geminus Volar Distal Radius Plate System is substantially equivalent to predicate devices currently marketed. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:

The Skeletal Dynamics Geminus Volar Distal Radius Plate System is substantially equivalent to the predicate device identified in this premarket notification.