November 13, 2025

Skeletal Dynamics Inc
Daniel Gallego
Regulatory Affairs Specialist
7300 North Kendall Drive
Suite 800
Miami, Florida 33156

Re: K252949
Trade/Device Name: Geminus Volar 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 15, 2025
Received: September 16, 2025

Dear Daniel Gallego:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252949

Please provide the device trade name(s).

Geminus Volar Distal Radius Plating System

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252949
510(k) SUMMARY
Skeletal Dynamic's
GEMINUS Volar Distal Radius Plating System

Submitter

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E-mail : dgallego@skeletaldynamics.com
Contact Person: Daniel E. Gallego
Date Prepared: November 12th, 2025

Name and Classification

Trade Name: GEMINUS Volar Distal Radius Plating System
Common Name: Plate, Fixation, Bone.
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories (Primary), Smooth or threaded metallic bone fixation fastener.
Classification Number: 21 CFR §888.3030 (Primary), 21 CFR §888.3040
Regulatory Class: Class II
Product Code: HRS (Primary), HWC

Predicate Devices

- Geminus Volar Distal Radius Plate System (K182492)

Reference Device

- Sponger Cable System, Modification - Pioneer Surgical Technology Inc. Sternal Cable System (K935481)
- Geminus Fossa Specific Plate System (K122310)
- Geminus Fossa Specific Plate System (K122737)
- Proximal Humerus Fixation System (K242436)
- Protean Fragment Plating System (K241815)
- Synthes Titanium Alloy Volar Distal Radius Plate System (K963798)

Device Description

The current Geminus Volar Distal Radius Plating System includes medical grade titanium alloy (Ti 6Al-V4 ELI) bone plates offered in 12 sizes, an ulnar hook plate, Cobalt-Chromium-Molybdenum (CoCrMo) and titanium alloy (Ti 6Al-V4 ELI) bone screws and pegs, and specialized instrumentation for the repair of distal radius and osteotomies. The system also includes the Radial Hook Plate extensions to buttress a volar marginal fragment, and the Buttress Button assembly to capture and hold small dorsal corner fractures.

The implants and instruments are provided non-sterile and shall be sterilized at the health care facility.

The Geminus Volar Distal Radius Plating System is comprised of:

System Components	Material(s)	Standard(s)
Geminus Volar Distal Radius Plates	Ti 6Al-V4 ELI	ASTM F136
Locking Smooth Pegs **Locking Threaded Pegs** **High Compression Locking Pegs** **Non-Locking Threaded Pegs** **Cortical Non-Locking Screws** **Cortical Locking Screws**	Ti 6Al-V4 ELI	ASTM F136
Washer Button	Ti 6Al-V4 ELI	ASTM F136
Polyaxial Locking Screws	CoCrMo	ASTM F1537
Geminus Hook Plate Screws	Ti 6Al-V4 ELI	ASTM F136
Geminus Ulnar Hook Plate	Ti 6Al-V4 ELI	ASTM F136
Geminus Radial Hook Plate	Ti 6Al-V4 ELI	ASTM F136
Geminus Buttress Button Assembly	Ti 6Al-V4 ELI CP Ti Grade 2	ASTM F136 ASTM F86

Indications for Use

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

Substantial Equivalence

The Geminus Volar Distal Radius Plating System is substantially equivalent to the Geminus Volar Distal Radius Plate System (K182492). The subject and predicate devices have the same intended use, and only minor differences in the technological characteristics are identified. These differences do not present any concerns related to the safety or effectiveness of the device as demonstrated by the performance testing.

Comparison of Technological Characteristics with the Predicate Device

The subject Geminus Volar Distal Radius Plating System is substantially equivalent to the predicate Geminus Volar Distal Radius Plate (K182492). The subject device consists of the same types of components (bone plates and bone screws) as the predicate device. Similarities in material, manufacturing process, performance, sterility, and packaging are demonstrated in this premarket notification.

The primary difference between the subject device and its predicate device is the introduction of the buttress button assembly and radial hook plate extensions. However, the addition of these accessories do not raise any concerns of safety or effectiveness as demonstrated by the performance testing results.

Performance Testing

Based on the similarities in indications for use, technological characteristics, and the results of engineering analysis and mechanical performance testing, the Skeletal Dynamics Geminus Volar Distal Radius Plating System has been demonstrated to be substantially equivalent to the predicate device. Construct testing, including both static and dynamic testing, confirmed that the subject device and its accessories met the established acceptance criteria. Therefore, the subject device does not raise new questions of safety or effectiveness and is considered as safe and effective as the legally marketed predicate device.

Additionally, Skeletal Dynamics Inc has conducted testing to assess the safety and compatibility of the Skeletal device portfolio in a magnetic resonance (MR) environment and provide labeling recommendations for the 1.5 T and 3 T clinical scanners. Magnetically induced displacement force per ASTM F2052, Magnetically induced torque per ASTM F2213, MR image artifact per ASTM F2119, and radiofrequency (RF) induced heating per ASTM F2182 were evaluated following the FDA Guidance for Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (FDA-2019-D-2837).

Conclusions

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