K122310

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510(k) SUMMARY

SKELETAL DYNAMICS, LLC's
GEMINUS VOLAR DISTAL RADIUS PLATE SYSTEM

JAN 18 2013

January 11, 2013

Submitter:
Skeletal Dynamics, LLC
8905 SW 87 Avenue
Suite 201
Miami, FL 33176
Tel: (305) 596-7585
Fax: (305) 596-7591
Contact: Ana M. Escagedo, President
Email: aescagedo@skeletaldynamics.com
Establishment registration number: 3006742481

Trade name, common name, classification:

Trade names	Geminus Volar Distal Radius Plate System
Common name:	Plate, fixation, bone
Classification:	21 CFR §888.3030, Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Product code:	HRS
Class:	Class II

Predicate devices:
Skeletal Dynamics GEMINUS Volar Distal Radius Plate (K111620, K122737), Synthes Distal Radius Plate (K963798), and Medpac SFC (K951303)

Description of the device:
The 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 Plate is available in 6 sizes and is made of medical grade titanium alloy. Cortical locking screws affix the plate to the diaphysis, fixed angle pegs are used for distal bone fragments. The titanium Hook Plate Extension locks to the plate by a means of titanium screw. 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
- Cannulated cobalt chrome polyaxial locking screws
- Titanium alloy hook plate extension
- Stainless steel k-wires (for provisional fixation not for implantation)
- System specific instrumentation.

Intended use:
The Skeletal Dynamics GEMINUS Volar Distal Radius Plate System is intended for fixation of fractures and osteotomies of the distal radius.

Summary of technological characteristics / substantial equivalence:
The substantial equivalence of the Skeletal Dynamics Geminus Volar Distal Radius Plate System to the predicate devices are 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:
Preclinical analysis and testing demonstrated that the Skeletal Dynamics Geminus Volar Distal Radius Plate System is substantially equivalent to the predicate devices which are currently marketed. Mechanical testing which established equivalency included static and dynamic testing. Therefore, the subject device is equivalent to the legally marketed predicate devices.

Conclusion
The Skeletal Dynamics Geminus Volar Distal Radius Plate System has the same intended use and indications, principles of operation and technological characteristics as the predicates. The minor difference in the hook plate extension does not raise any new questions of safety or effectiveness. Performance data demonstrates that the Geminus Volar Distal Radius Plate System is as safe and effective as the Geminus Volar Distal Radius Plate System (K111620, K122737) and therefore is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Skeletal Dynamics, LLC
% Ms. Ana M. Escagedo
President
8905 SW 87 Avenue, Suite 201
Miami, Florida 33176

Letter dated: January 18, 2013

Re: K122310
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: November 30, 2012
Received: December 3, 2012

Dear Ms. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122310

Device Name: GEMINUS Volar Distal Radius Plate System

Indications for Use:

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

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
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Division of Orthopedic Devices