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510(k) SUMMARY

SKELETAL DYNAMICS, LLC's
GEMINUS VOLAR DISTAL PLATE SYSTEM

October 2, 2012

OCT 3 2012

Submitter:
Skeletal Dynamics, LLC
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Contact: Ana M. Escagedo, President
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Establishment registration number: 3006742481

Trade name, common name, classification:

Trade names	Skeletal Dynamics 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)
Synthes Titanium Alloy Volar Distal Radius Plate System (K963798)
Hand Innovations Multidirectional Threaded Peg (K060864)

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 cannulated cobalt chrome polyaxial locking screws for trajectories different than those of the fixed angled bone plates.

The GEMINUS Plate System is available in 6 sizes and is made of medical grade titanium alloy. Cortical locking 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 Skeletal Dynamics GEMINUS Plate System is comprised of:

- Titanium alloy plates, washers and screws
- Cannulated cobalt chrome polyaxial locking screws
- 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 device 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:
Static and fatigue testing was performed which shows that the Geminus Volar Distal Radius Plate System is equivalent to the cleared Geminus Volar Distal Radius Plate System (K111620).

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 predicate. The minor differences in the addition of a cobalt chrome polyaxial locking screw (the same material as the Hand Innovations Multidirectional Threaded Peg (K060864)) do 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 Skeletal Dynamics Volar Distal Radius Plate System (K111620) and the Synthes Titanium Alloy Volar Distal Radius Plate System (K963798). Thus, the Geminus Volar Distal Radius Plate System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 3 2012

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

Re: K122737
Trade/Device Name: Skeletal Dynamics 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 5, 2012
Received: September 6, 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122737

Device Name: Skeletal Dynamics Fossa Specific Plate System

Indications for Use:

The Skeletal Dynamics GEMINUS Fossa Specific 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122737