APR 0 7 2014

skeletal dynamics

510(k) Summary of Safety and Effectiveness
Skeletal Dynamics Protean Fragment Plate System

March 11, 2014

Submitter:
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Establishment Registration Number: 3006742481

Name and Classification:

Name	Protean Fragment Plate System
Common Name	Plate, fixation, bone
Classification	21 CFR §888.3030
Product Code	HRS
Class	Class II

Predicate Devices:
DePuy Small Bone Locking Plate System (K081546)

Description of the Device:
The Skeletal Dynamics Protean Fragment Plate System is a set of titanium bone plates designed for stabilization and repair of small bone fragments. Included in the set are titanium bone screws, fixation pegs, cobalt chrome cannulated polyaxial screws, and specialized instrumentation.

The Fragment Plates are available in 3 configurations and are made of medical grade titanium alloy. The system is provided non-sterile and is sterilized in the user facility.

The Skeletal Dynamics Protean Fragment Plate System is comprised of:

- Titanium alloy plates and screws
- Cobalt chrome polyaxial screws
- Stainless steel K-wires (for provisional fixation not for implantation)
- System specific instrumentation.

Intended Use:
The Skeletal Dynamics Protean Fragment Plate System is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, and pelvis, particularly in osteopenic bone.

Summary of Technological Characteristics / Substantial Equivalence:
The substantial equivalence of the Skeletal Dynamics Protean Fragment 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:
Preclinical analysis and testing demonstrated that the Skeletal Dynamics Protean Fragment Plate System is substantially equivalent to the predicate device currently marketed. Mechanical testing which established equivalency included static and dynamic testing. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:
The Skeletal Dynamics Protean Fragment Plate System is substantially equivalent to the predicate device identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 7, 2014

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

Re: K140372
Trade/Device Name: Protean Fragment 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: February 19, 2014
Received: February 21, 2014

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 contact 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. 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.

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,

Ronald P. Jean -S 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): K140372

Device Name: Protean Fragment Plate System

Indications For Use: The Skeletal Dynamics Protean Fragment Plate System is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, and pelvis, particularly in osteopenic bone.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Division of Orthopedic Devices