



**510(k) Summary of Safety and Effectiveness
Skeletal Dynamics Headless Compression Screw System**

September 9, 2011

Submitter:

Skeletal Dynamics, LLC
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Establishment Registration Number: 3006742481

Trade Name, Common Name, Classification:

| | |
|----------------|-----------------------------------|
| Trade Names | Headless Compression Screw System |
| Common Name | Screw, fixation, bone |
| Classification | 21 CFR §888.3040 |
| Product Code | HWC |
| Class | Class II |

Predicate Devices:

HBS Headless Bone Screw (K030302)

Description of the Device:

The Skeletal Dynamics Headless Compression Screw System consists of 2.5mm and 3.5mm cannulated titanium screws and specialized instrumentation. The 2.5mm screw is available in 7 length configurations between 12mm - 24mm, with increments of 2mm. The 3.5mm screw is available in 7 length configurations between 14mm - 26mm, with increments of 2mm.

The system is provided non-sterile and is sterilized in the user facility.

Intended Use:

The Skeletal Dynamics Headless Compression Screw System is intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized screw. Examples include:

Scaphoid fractures, lunate fractures, capitate fractures, trapezial fractures, metacarpal and metatarsal fractures, phalangeal fractures, radial head

fractures, ulnar styloid fractures, osteo-chondral fractures, small joint fusions, carpal fractures and non-unions, capitellum fractures, distal radius fractures, humeral head fractures, glenoid fractures, intercarpal fusions, interphalangeal fractures, metatarsal osteotomies, tarsal fusions, malleolar fractures, patellar fractures, odontoid fractures, and mandibular fractures.

Summary of Technological Characteristics / Substantial Equivalence:

The substantial equivalence of the Skeletal Dynamics Headless Compression Screw 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 compressive force testing demonstrated that the Skeletal Dynamics Headless Compression Screw is substantially equivalent to the predicate device which is currently marketed. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:

The Skeletal Dynamics Headless Compression Screw System is substantially equivalent to the predicate device identified in this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

DEC 13 2011

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

Re: K112672

Trade/Device Name: Headless Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: September 9th, 2011
Received: September 14th, 2011

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" (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,



for 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

510(k) Number (if known): K112672

Device Name: Headless Compression Screw System

Indications For Use: The Skeletal Dynamics Headless Compression Screw System is intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized screw. Examples include:

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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)

Michael Chas for MxM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1

510(k) Number K112672