February 23, 2018

Orthovestments, LLC
Robert Weinstein
Managing Partner
1640 Powers Ferry Bldg 9
Marietta, Georgia 30067

Re: K173693
Trade/Device Name: Orbitum Bone Staple Implant, X and VI
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: November 13, 2017
Received: December 1, 2017

Dear Robert Weinstein:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173693

Device Name

Orbitum Bone Staple Implant, X and VI

Indications for Use *(Describe)*
The ORBITUM X and VI Bone Staple is indicated for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Orbitum X and VI implants are intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis Akin osteotomy, midfoot and hindfoot arthrodesis or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Orthovestments, LLC

1630 Powers Ferry Road Bldg 23, Suite 100, Marietta, GA 30067 l p (404) 617-6939

510(k) Summary

As required by section 807.92(c)

December 1, 2017

Orthovestments, LLC is requesting marketing clearance for the Orbitum Bone Staple.

A. Sponsor/Manufacturer: Orthovestments, LLC
Dr. Robert Weinstein, Managing Partner

B. Trade Name: Orbitum Bone Staple Implant, X and VI
Common Name: Fixation Staple
Classification Name: Single/multiple component metallic bone fixation appliance and accessories (21 CFR 888.3030 Class II, Product Code JDR)

C. Predicate Device: K043059 – Compression Staple and Simple Staple (Wright Medical Technologies);
K121277 – Z –staple (Z=medical Gmbh);
K161587 – Memodyn Staple (Telos Medical)

D. Device Description:
Orbitum Bone Staple Implants, X and VI, have either radial or hourglass shaped superior profiles in three distinct sizes to coincide with the surgical approach. The legs of the device are configured to create compression upon implantation.
Orbitum Bone Staple Implants , are manufactured from Grade 23 Titanium (Ti-6Al-4V ELI); manufactured according to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications.

E. Intended Use:

The *ORBITUM* X and VI Bone Staple is indicated for fracture and osteotomy fixation and joint arthrodesis of the hand and foot

ORBITUM X and VI Implants are intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodesis or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

F. Technological Characteristics:
The technological characteristics of the, *ORBITUM* X and VI Bone Staple are equivalent to the predicate device, except for the superior profile diameters and quantity / size of legs .

G. Non-clinical Testing:
Testing according to ASTM F564 was performed on the *ORBITUM* Bone Staple to establish equivalency to the predicate device. The tests included static compression bending, dynamic compression bending and axial pull-out testing.
ORBITUM Bone Staple Implants, are equivalent in mechanical function and properties to the predicate device, establishing equivalency in safety and effectiveness.

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H. Conclusion:

The testing completed as well as a comparison of the technological characteristics has demonstrated that the *ORBITUM* X and VI Bone Staples, are substantially equivalent to the predicate device(s).