



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

Phalanx Innovations
% Ms. Cheryl Wagoner
Principal Consultant
Wagoner Consulting LLC
P.O. Box 15729
Wilmington, North Carolina 28408

April 29, 2016

Re: K160304

Trade/Device Name: OsteoBullet Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 3, 2016
Received: February 4, 2016

Dear Ms. Wagoner:

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 Parts 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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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 -S

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)

K160304

Device Name

OsteoBullet Compression Screw

Indications for Use (Describe)

OsteoBullet Compression Screw is intended to maintain alignment and fixation of bone fractures, non-unions, osteotomies, or arthrodeses of small bones in the hand and foot.

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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510(k) Summary
(as required by 21 CFR 807.92)

Date Prepared	April 26, 2016
Manufacturer	Phalanx Innovations
Address	200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 101
Fax	678-669-2188
Contact Person	Daniel Lanois General Manager
Address	Phalanx Innovations 200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 101
Fax	678-669-2188
email	daniel@phalanxinnovations.com

Trade Name	OsteoBullet Compression Screw
Common Name	Bone Screw or Internal Fixation Device (non-spinal)
Panel Code	Orthopaedics/87
Classification Name	Smooth or threaded metallic bone fixation fastener
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	HWC

Name of Predicate/Reference Device	510(k) #	Manufacturer
Ti6® Internal Fixation System (cleared as Koby Surgical Internal Fixation System)	K060026	Integra (cleared under Koby Surgical)
Inion Freedom Screw™	K123672	Inion Oy
DARCO Headless Compression Screw (Referenc)	K080850	Wright Medical Technology, Inc.

Description	The OsteoBullet Compression Screw has a wide range of diameters and lengths for use in a variety of fracture treatments. Implants are available as cannulated or non-cannulated and made from Titanium 6AL-4V ELI (ASTM F136) or Zeniva™ ZA-500 PEEK (ASTM F2026) and range in size from Ø3 to 7 mm in diameter and 16 to 105 mm in length. Implants are provided sterile and are for single use only. The system includes instrumentation to aid in delivery of the implants including drill guides, guide wires, depth gauge, manual drills, manual stop drills, taps, and drivers.
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Indications and Intended Use	OsteoBullet Compression Screw is intended to maintain alignment and fixation of bone fractures, non-unions, osteotomies, or arthrodesis of small bones in the hand and foot.
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Technological Characteristics	Documentation was provided to demonstrate that the Subject device poses no new risks when compared to the predicate and reference devices presented in this application. The Subject device is identical to the predicate devices in intended use and similar regarding indications for use, materials, technological characteristics, and labeling.
Performance Data	Axial pushout, torque to failure testing (per ASTM F543-13) confirmed that the Subject device performed as intended and is at least equivalent to the predicate devices. Static 3-point bending and dynamic 3-point bending per ASTM F1264-14 further confirmed the performance and substantial equivalence of the Subject device.
Conclusion	Based on the intended use, indications for use, technological characteristics, materials, performance data, and comparison to predicate devices, the Subject device has been shown to be substantially equivalent to legally marketed predicate devices.