## 510(K) SUMMARY

## Integra® Titanium Bone Wedge

**Submitter's name and address:**

Ascension Orthopedics
8700 Cameron Road
Austin, TX 78754 USA

**Contact person and telephone number:**

Kyla Kara
Associate, Regulatory Affairs
Telephone: 609.936.6926
Facsimile: 609.275.9445

AUG 07 2013

**Date Summary was prepared:**

May 9, 2013

**Name of the device:**

| | |
|---|---|
| Proprietary Name: | Integra® Titanium Bone Wedge |
| Common Name: | Bone Wedge |
| Classification Name: | Plate, Fixation, Bone (21CFR §888.3030, Product Code HRS)<br>Screw, Fixation, Bone (21CFR §888.3040, Product Code HWC) |
| Classification Panel: | Orthopedic |

**Substantial Equivalence:**

The Integra® Titanium Bone Wedge is substantially equivalent in function and intended use to the predicate device detailed in the following table.

| 510(k) Number | Product Code | Trade Name | Manufacturer |
|---|---|---|---|
| K093950 | HRS; HWC | BIOFOAM™ Bone Wedge | Wright Medical Technology, Inc. |

**Device Description:**

The Integra® Titanium Bone Wedges are a series of wedge-shaped devices intended to be used for angular correction of small bones in the ankle and foot. The Integra® Titanium Bone Wedges are constructed from commercially pure titanium formed into a cancellous-like structure, and are offered in a variety of sizes and shapes to correct various skeletal deformities in the foot. The Integra® Titanium Bone Wedges are intended to be used with ancillary plating fixation.

**Indications for Use:**

The Integra® Titanium Bone Wedges are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Integra® Titanium Bone Wedges are intended for use with ancillary plating fixation.

The Integra® Titanium Bone Wedges are not intended for use in the spine.

**Substantial Equivalence Comparison:**

Components of the Integra® Titanium Bone Wedge are similar in design and materials to the predicate device, BIOFOAM™ Bone Wedge (K093950).

**Testing and Test Results:**

Mechanical testing, including expulsion, abrasion, corrosion, static compression, and compressive fatigue, as well as biocompatibility testing were performed on the proposed device. The results of these verification activities demonstrate that the Integra® Titanium Bone Wedges are safe for the intended use, and are substantially equivalent to the predicate device identified.

**Conclusion:**

The design features, material, and intended use of the Integra® Titanium Bone Wedges are substantially equivalent to the predicate device, BIOFOAM™ Bone Wedge (K093950). The safety and effectiveness of the Integra® Titanium Bone Wedge is adequately supported by the substantial equivalence information, materials information, and performance data provided within this Premarket Notification submission.

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

August 7, 2013

Ascension Orthopedics
Ms. Kyla Kara
Associate, Regulatory Affairs
8700 Cameron Road
Austin, Texas 78754

Re: K131360
Trade/Device Name: Integra® Titanium Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 19, 2013
Received: July 22, 2013

Dear Ms. Kara:

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" (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,

For Erin I. Keith

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):** K131360

**Device Name:** Integra® Titanium Bone Wedge

**Indications For Use:**

The Integra® Titanium Bone Wedges are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Integra® Titanium Bone Wedges are intended for use with ancillary plating fixation.

The Integra® Titanium Bone Wedges are not intended for use in the spine.

Prescription Use _X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Page 1 of 1