

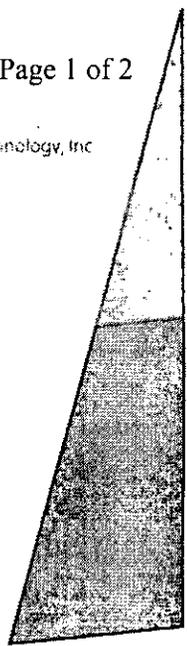
09 2014



Headquarters  
Wright Medical Technology, Inc

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Memphis, TN 38117

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**510(K) SUMMARY**

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the WMT BIOFOAM® Bone Wedge.

**(a)(1). Submitted By:** Wright Medical Technology, Inc.  
1023 Cherry Road  
Memphis, TN 38117

**Date:** May 29, 2014

**Contact Person:** Val Myles  
Regulatory Affairs Specialist I  
Office - (901) 290-5162  
Fax - (901) 867-4190

**(a)(2). Proprietary Name:** BIOFOAM® Bone Wedge

**Common Name:** Bone Wedge

**Classification Name and Reference:** 21 CFR 888.3030 – Class II

**Device Product Code, Device Panel:** HRS, HWC

**(a)(3). Predicate Device:** K093950: BIOFOAM® Bone Wedge

**(a)(4). Device Description**

The BIOFOAM® Bone Wedge is a titanium metal foam wedge used for angular correction of small bones of the foot. It is offered with varying widths and thicknesses to accommodate a variety of small bone applications.

**(a)(5). INTENDED USE**

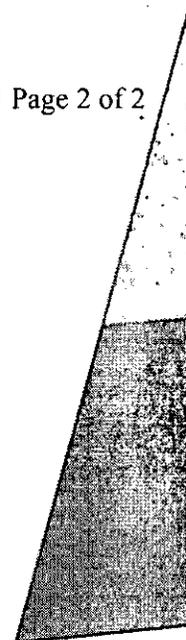
The indications for use for the subject devices convey the same overall intended use as the predicate device and were only modified to provide additional clarification, such as examples of use or the area of the foot in which the device can be used.

The BIOFOAM® Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Cotton and Evans Wedges:
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Opening wedge of Medial Cuneiform or Cotton osteotomies



- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Metatarsal/Cuneiform arthrodesis
- Midfoot Wedges:
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)



This device is intended for use with ancillary fixation.  
The BIOFOAM<sup>®</sup> Bone Wedge is not intended for use in the spine.

**(a)(6). Technological Characteristics Comparison**

The BIOFOAM<sup>®</sup> Bone Wedge is technologically substantially equivalent to the predicate device. The subject devices include the addition of the midfoot wedge design and larger cotton wedge sizes. The subject and predicate devices are identical in material.

**(b)(1). Substantial Equivalence – Non-Clinical Evidence**

A testing rationale related to compression and fatigue testing was provided to support the equivalence of the subject device and shows that no new worst-case devices are introduced in this system. The safety and effectiveness of the BIOFOAM<sup>®</sup> Bone Wedge is adequately supported by the testing rationale, substantial equivalence information, materials information and comparison of design characteristics provided within this premarket notification.

**(b)(2). Substantial Equivalence – Clinical Evidence**

N/A

**(b)(3). Substantial Equivalence – Conclusions**

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.



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

July 9, 2014

Wright Medical Technology, Incorporated  
Ms. Val Myles  
Regulatory Affairs Specialist I  
1023 Cherry Road  
Memphis, Tennessee 38117

Re: K140531  
Trade/Device Name: BIOFOAM<sup>®</sup> 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: June 4, 2014  
Received: June 5, 2014

Dear Ms. Myles:

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 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" (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 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,

**Lori A. Wiggins**

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)  
K140531

Device Name  
BIOFOAM® Bone Wedge

*Indications for Use (Describe)*

The BIOFOAM® Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Cotton and Evans Wedges:
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Opening wedge of Medial Cuneiform or Cotton osteotomies
  - Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
  - Metatarsal/Cuneiform arthrodesis
  
- Midfoot Wedges
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

This device is intended for use with ancillary fixation.  
The BIOFOAM® Bone Wedge is not intended for use in the spine.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Elizabeth L. Frank -S**

Division of Orthopedic Devices