



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Biomet Incorporated
Ms. Julie Largent
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46582

March 9, 2016

Re: K160058

Trade/Device Name: Biomet Variable Pitch Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 11, 2016
Received: January 12, 2016

Dear Ms. Largent:

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)

K160058

Device Name

Variable Pitch Compression Screw System

Indications for Use (Describe)

The Variable Pitch Compression Screw System is indicated for alignment and stabilization of small bone fractures.

Specifically:

- Fixation of small bones, such as those in the foot, ankle, wrist, elbow and hand for treatment of fractures, non-unions, or mal-unions
- Ligament reconstruction
- Osteochondritis dissecans
- Arthrodesis of the foot, ankle, wrist, elbow and hand
- Small bone osteotomies, including first metatarsal head osteotomy, metatarsal osteotomies, phalangeal osteotomies, and carpal/metacarpal osteotomies.

These procedures may be indicated as part of trauma, deformity, osteoarthritis, and rheumatoid arthritis.

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Variable Pitch Compression Screw System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact: Julie Largent
Regulatory Affairs Specialist
305-269-6391

Date: March 3, 2016

Subject Device: Trade Name: Biomet Variable Pitch Compression Screw System
Common Name: Screw, Fixation, Bone

Classification Name:

- HWC – Smooth or threaded metallic bone fixation fastener - (21 CFR 888.3040)

Legally marketed devices to which substantial equivalence is claimed:

- EBI, LLC¹ BioDrive Micro – K092670

Device Description

The Biomet Variable Pitch Compression Screw System offers headless, cannulated compression screws in three different diameters in various lengths. The screws are manufactured from Titanium Alloy (ASTM F136) and are either color anodized or passivated for ease of size identification. The system will also include instrumentation to aid the user in alignment and stabilization of fractures to the skeletal system.

Intended Use and Indications for Use

The Variable Pitch Compression Screw System is indicated for alignment and stabilization of small bone fractures.

Specifically:

- Fixation of small bones, such as those in the foot, ankle, wrist, elbow and hand for treatment of fractures, non-unions, or mal-unions
- Ligament reconstruction
- Osteochondritis dissecans
- Arthrodesis of the foot, ankle, wrist, elbow and hand

¹ K092670 is officially registered under EBI, LLC D/B/A Biomet Trauma

- Small bone osteotomies, including first metatarsal head osteotomy, metatarsal osteotomies, phalangeal osteotomies, and carpal/metacarpal osteotomies.

These procedures may be indicated as part of trauma, deformity, osteoarthritis, and rheumatoid arthritis.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The Intended Use of the Biomet Variable Pitch Compression Screw System is the same as the intended uses cleared in the predicate BioDrive Micro Screws, K092670.
- **Indications for Use:** The Indications for Use of the Biomet Variable Pitch Compression Screw System are the same as the predicate device.
- **Materials:** The Biomet Variable Pitch Compression Screw System screws are manufactured from Titanium Alloy (Ti-6Al-4V ELI ASTM F136) and the predicate screws are similarly manufactured from a Titanium alloy. The screws are either passivated or color anodized for ease of identification.
- **Design Features:** The design features for the Biomet Variable Pitch Compression Screw System are similar to currently marketed devices cleared in K092760 including the size (diameter), length, cannulation, and pitch. The design differences have not identified any issues that would impact the safety and effectiveness of the devices.
- **Sterilization:** The implants are offered to the user either in the sterile or non-sterile configuration. The non-sterile devices will be required to be steam sterilized by the user prior to use while the sterile implants will be terminally sterilized by gamma irradiation. These sterilization configurations are the same as the predicate devices currently marketed and cleared via K092670.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - Non-clinical performance testing included mechanical testing to ASTM F543 to determine substantial equivalence of the Biomet Variable Pitch Compression Screw System. Results indicate that the subject system is substantially equivalent to legally marketed devices.
- Clinical Tests
 - No clinical tests are provided for basis of substantial equivalence.

Substantial Equivalence Conclusion

The Biomet Variable Pitch Compression Screw System has shown to be substantially equivalent to the predicate device. Results of non-clinical tests and the similarities with legally marketed predicate devices indicate the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.