JUN 0 3 2014

Section 5 – 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitted by: Biomet Manufacturing Corp.
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Contact Person: Victoria Scheitlin, Regulatory Affairs Specialist

Date Prepared: April 2, 2014

Proprietary Name: Biomet Cannulated Screw System

Common Name: Screw, Fixation, Bone

Classification Name: Smooth or threaded metallic bone fixation fastener. (21 CFR § 888.3040/HWC)

Predicate Devices: Biomet's Cannulated Screw System is substantially equivalent to currently marketed BioDrive Cannulated Screw System (K082874), DePuy/Ace 8.0mm Cannulated Cancellous Bone Screw (K926047), DePuy/Ace Cannulated Self Tapping Cancellous Bone Screw (K903810), Ace/DePuy Ace Cancellous Bone Screw (K872859), Synthes Sterile 4.5mm Cannulated Screws (K963172), Synthes Sterile 3.5mm and 4.0mm Cannulated Screws (K963192), Synthes 6.5mm Cannulated Screw (K021932), Synthes 7.3mm Cannulated Slipped Capital Femoral Epiphysis Screws (K092909).

Device Description: The Biomet Cannulated Screw System consists of bone screws, associated washers, which are manufactured from Titanium-6 Aluminum-4 Vanadium (Ti-6AL-4V), and corresponding instruments are used to aid in the alignment and stabilization of fractures to the skeletal system.

Indications for Use:	**Small Cannulated Screws (4.0mm and smaller diameter) are intended for use in:** 1. Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow. 2. Arthrodesis of the foot, wrist and elbow. 3. Small and long bone osteotomies. 4. Fracture fixation of small bones, small bone fragments and long bones. **Large Cannulated Screws (5mm and larger in diameter) are intended for use in:** 1. Fixation of fractures in long bones and long bone fragments. 2. Long bone osteotomies (femur, tibia, foot, ankle, olecranon). 3. Arthrodesis, and fracture fixation of the foot and ankle, such as Jones fractures of the fifth metatarsal, and Calcaneal fractures. **Large Cannulated Screws (6.5mm and larger in diameter) are intended for use in:** 1. Slipped capital femoral epiphysis 2. Pediatric femoral neck fractures 3. Tibial plateau fractures 4. SI joint disruptions 5. Intercondylar femur fractures 6. Subtalar arthrodesis 7. Fixation of pelvis and iliosacral joint.
Technological Characteristics:	The technological characteristics of the Biomet Cannulated Screw System are similar to the predicate devices including design, dimensions, and material. The Biomet Cannulated Screw System screws and washers are fabricated from Ti-6Al-4V alloy per ASTM F136. Ti-6Al-4V alloy is a commonly used material in orthopedic implants, and is a material that was used in predicate devices cleared in K082874, K903810, K926047, and K872859.
Summary of Substantial Equivalence:	The Biomet Cannulated Screw System is substantially equivalent to currently marketed devices. No new issues of safety or efficacy have been raised.
Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence:	Non-clinical performance testing included cadaver evaluation and MRI justification. Mechanical tests per ASTM F543 that were performed to determine substantial equivalence of the Biomet Cannulated Screws including torsional, axial pullout and driving torque. Results indicate that the subject screws are substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.

Summary of Clinical Tests Conducted for Determination of Substantial Equivalence and/or of Clinical Information:	None provided as a basis for substantial equivalence.
Conclusions Drawn From Non-Clinical And Clinical Data	The Biomet Cannulated Screw System has been shown to be substantially equivalent to the predicate devices. Results of preclinical tests/engineering justification and the similarities with legal marketed predicated devices indicate the device will perform within the intended use and no new issues of safety or effectiveness have been raised.

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

June 3, 2014

Biomet Manufacturing Corporation
Ms. Victoria Scheitlin
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K140891
Trade/Device Name: Biomet Cannulated 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: April 15, 2014
Received: April 16, 2014

Dear Ms. Scheitlin:

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,

Ronald P. Jean -S for

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

Enclosure

Section 4 – Indications for Use Statement

510(k) Number: K140891

Device Name: Biomet Cannulated Screw System

Indications For Use:

Small Cannulated Screws (4.0mm and smaller diameter) are intended for use in:

1. Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow.
2. Arthrodesis of the foot, wrist and elbow.
3. Small and long bone osteotomies.
4. Fracture fixation of small bones, small bone fragments and long bones.

Large Cannulated Screws (5mm and larger in diameter) are intended for use in:

1. Fixation of fractures in long bones and long bone fragments.
2. Long bone osteotomies (femur, tibia, foot, ankle, olecranon).
3. Arthrodesis, and fracture fixation of the foot and ankle, such as Jones fractures of the fifth metatarsal, and Calcaneal fractures.

Large Cannulated Screws (6.5mm and larger in diameter) are intended for use in:

1. Slipped capital femoral epiphysis
2. Pediatric femoral neck fractures
3. Tibial plateau fractures
4. SI joint disruptions
5. Intercondylar femur fractures
6. Subtalar arthrodesis
7. Fixation of pelvis and iliosacral joint.

Prescription Use X AND/OR Over-the-Counter ___
(Per 21 CFR 801 Subpart D) (21 CFR 801 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