510(k) SUMMARY

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

Submitter Information	
Name	Biomet Sports Medicine
Address	56 East Bell Drive P.O. Box 587 Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 372-1718
Establishment Registration Number	1825034
Name of contact person	Elizabeth Wray / Senior Regulatory Affairs Specialist
Date prepared	August 7, 2012
Name of device	
Trade or proprietary name	WasherLoc™ and No-Profile Screw and Washer Systems
Common or usual name	Soft Tissue Fixation Devices
Classification name	Fastener, fixation, nondegradable, soft tissue and smooth or threaded metallic bone fixation fastener
Classification panel	Orthopedic
Regulation	888.3040
Product Code(s)	MBI or HWC
Legally marketed device(s) to which equivalence is claimed	WasherLoc™, Ligament Washer, Lo-Profile™, Heckman™, and Channel Ligament Screw Systems – Biomet Sports Medicine K981967 Cancellous Fixation Screw & Washer – Concept Inc., K871037
Reason for 510(k) submission	Addition of magnetic resonance (MR) compatibility language to the product labeling.
Device description	The WasherLoc™ and No-Profile Screw and Wahser Systems include titanium alloy (Ti-6Al-4V) screws and washers in various lengths and sizes. Both 4.5mm and 6.0mm diameter screws in lengths from 30mm to 70mm are available, with washer sizes in 14mm, 16mm, and 18mm diameters with and without spikes.
Intended use of the device	Soft Tissue Fixation

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Indications for use	Soft tissue fixation to bone, specifically during ligament reconstructive procedures.	
Summary of the technological characteristics of the device compared to the predicate		
Characteristic	WasherLoc™ and No-Profile Screw and Washer Systems (Modified Device)	Predicate – WasherLoc™, Ligament Washer, Lo-Profile™, Heckman™, and Channel Ligament Screw Systems (K981967)
Material	Titanium Alloy (Ti-6Al-4V)	K981967
Magnetic Resonance Information	MR Conditional	Not evaluated
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Summary of Technologies		
The WasherLoc™ and No-Profile Screw and Washer Systems have been evaluated for the effects of magnetic resonance (MR) and deemed MR Conditional.		
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 results of the MR evaluation indicated that the devices are MR Conditional.		

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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

October 18, 2013

Biomet Sports Medicine
Ms. Elizabeth Wray
Senior Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581

Re: K122437
Trade/Device Name: WasherLoc™ and No-Profile Screw and Washer Systems
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: October 8, 2013
Received: October 9, 2013

Dear Ms. Wray:

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" (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 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,

Mark N. Melkerson -S

Mark 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): K122437

Device Name: WasherLoc™ and No-Profile Screw and Washer Systems

Indications For Use:

Soft tissue fixation to bone, specifically during ligament reconstructive procedures.

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices