K111564 (1/2)

BIOMET SPORTS MEDICINE

JUN 16 2011

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 / Regulatory Project Manager Victor Rodgers / Director of Quality, Clinical, and Regulatory Affairs
Date prepared	May 31, 2011
Name of device	
Trade or proprietary name	MaxFire™ and MaxFire™ MarXmen™ Meniscal Repair Devices
Common or usual name	Suture Anchor
Classification name	Fastener, Fixation, Nondegradable, Soft Tissue
Classification panel	Orthopedic
Regulation	888.3040
Product Code(s)	MBI
Legally marketed device(s) to which equivalence is claimed	Arthrotek® MaxFire™ Meniscal Repair Device – K061776
Reason for 510(k) submission	Device Modification
Device description	The Maxfire™ Meniscal Repair Device is a permanent fixation anchor composed of a size 2-0 polyethylene/polypropylene ZipLoop™ construct with two #5 polyester sleeves. The ZipLoop™ construct is an adjustable loop created with a single piece of fiber material. When the ZipLoop™ is pulled tight, the sleeves lock against the meniscal tissue, pulling the tear together. The sleeves control the size of the knot ensuring that the anchor does not become too small and pull through the meniscal tissue. The anchors are pre-loaded onto an insertion instrument. The inserter allows for single entry into the joint. Once in the joint, the inserter will pierce the meniscus at the desired location. The insertion device is available as an in-line inserter or a pistol-grip inserter, the MaxFire™ MarXmen™ Meniscal Repair Device. This allows separate deployment of the anchors, one on each side of the tear. After the second anchor has been deployed, the

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	knotted end of the ZipLoop™ construct is gently pulled by the surgeon, allowing the meniscal tear to be compressed. The Maxfire™ anchor sits on the back side of the meniscus.	
Intended use of the device	Meniscal Repair	
Indications for use	The Biomet Sports Medicine™ Maxfire™ MarXmen™ Meniscal Repair Device is indicated for the repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.	
Summary of the technological characteristics of the device compared to the predicate		
Characteristic	MaxFire™ and MaxFire™ MarXmen™ Meniscal Repair Device (Modified Device)	Predicate – MaxFire™ Meniscal Repair Device (K061776)
Design	Two sleeves with a ZipLoop™ Construct.	Two loops with a sliding knot.
Material	Polyester Polyethylene/Polypropylene	K061776
Principal of operation	Deployment of anchors on each side of meniscal tear.	K061776
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Summary of Technologies		
The MaxFire™ and MaxFire™ MarXmen™ Meniscal Repair Devices have the same technological characteristics as the predicate except for slight modifications described within this 510(k). Testing was conducted to support the modifications and to determine substantial equivalence.		
Characteristic	Standard/Test	Results (Criteria Meets or Exceeds)
Fixation Strength	Pull-out Testing in comparison to predicate	Meets acceptance criteria as set by predicate fixation strength.
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 mechanical testing indicated that the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate device.		

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Sports Medicine
% Ms. Elizabeth Wray
Regulatory Product Manager
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

JUN 16 2011

Re: K111564
Trade/Device Name: Maxfire™ MarXmen™ Meniscal Repair Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 31, 2011
Received: June 7, 2011

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111564

Device Name: Maxfire™ MarXmen™ Meniscal Repair Device

Indications for Use:

The Biomet Sports Medicine™ Maxfire™ MarXmen™ Meniscal Repair Device is indicated for the repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.

Prescription Use ___YES___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO___ (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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111564