K103145(1/2)

BIOMET SPORTS MEDICINE

FEB - 9 2011

510(k) Summary

Preparation Date: February 9, 2010

Applicant/Sponsor: Biomet Sports Medicine

Contact Person: Robert R. Friddle
Regulatory Affairs Specialist

Proprietary Name: TunneLoc™ Tibial Fixation Device

Common Name: Soft tissue fixation device

Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue (21CFR §888.3040) MBI
Screw, Fixation, Bone (21CFR §888.3040) HWC

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K041274	Resorbable Interference Screw
K982497	Arthrotek Interference Screw
K083607	AperFix™ Tibial Implant with Inserter
K983560	Intratunnel Tibial Fixation Fastener

Device Description:
The Biomet Sports Medicine TunneLoc™ Tibial Fixation Device is a non-resorbable intratunnel implant intended to aid in arthroscopic ACL and/or PCL reconstructions. The inserter instrument provides a means to apply and hold tension to the soft tissue, align and drive the PEEK implant. A nitinol guide wire instrument is provided to aid in implant placement. The TunneLoc™ Tibial Fixation Devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures.

Intended Use:
The TunneLoc™ Tibial Fixation Device is intended for soft tissue fixation for the following indications:

To provide fixation of soft-tissue grafts within the tibial tunnel during anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) reconstruction.

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56 East Bell Drive
Warsaw, IN 46582

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Summary of Technologies:
The TunneLoc™ Implant design includes technological characteristics and indications similar or identical to the predicate devices. The conical shell with blunt wedge tip is similar to the tapered sheath of the predicate Intratunnel Tibial Fixation Fastener (K983560), while the cannulation and insertion over a guide wire are similar to the predicate Gentle Threads™ (K041274). The TunneLoc™ implant is composed of PEEK material like the predicate AperFix™ (K083607). Dimensional characteristics of a 7-10mm diameter range is available in the predicate Gentle Threads™ (K041274) and 30mm length available in all predicates. The TunneLoc™ inserter instrument provides a means to apply and hold tension to the soft tissue graft prior to and during implant insertion similar to the predicate Intratunnel Tibial Fixation Fastener (K983560) and AperFix™ (K083607) Instruments.

Non-Clinical Testing:
Non-clinical laboratory testing was performed to verify the fixation strength of the TunneLoc™ Tibial Fixation Devices in pullout tests using porcine tibia and bovine tendon test medium as compared to the predicate devices for specific indications for use. The test results indicate that the TunneLoc™ Tibial Fixation Devices provide equivalent pullout strength to the predicate devices and would be functional within their intended use.

Clinical Testing:
None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Biomet Sports Medicine
% Mr. Robert Friddle
Regulatory Specialist
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P.O. Box 587
Warsaw, Indiana 46581-0587

FEB 09 2011

Re: K103145
Trade/Device Name: TunneLoc™ Tibial Fixation Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: February 4, 2011
Received: February 7, 2011

Dear Mr. Friddle:

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): K103145

Device Name: TunneLoc™ Tibial Fixation Device

Indications For Use:

To provide fixation of soft-tissue grafts within the tibial tunnel during anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) reconstruction.

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)

for M Melkerson

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

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