K110879 (1/2)

BIOMET
SPORTS MEDICINE

AUG 19 2011

510(k) Summary

Preparation Date: June 6, 2011

Applicant/Sponsor: Biomet Sports Medicine

Contact Person: Elizabeth Wray / Regulatory Project Manager
Victor Rodgers / Director of Quality, Clinical, & Regulatory Affairs
574-267-6639

Proprietary Name: JuggerKnot™ Mini Soft Anchors

Common Name: Soft Tissue Fixation Device

Classification Name: Fastener, fixation, nondegradable, soft tissue
(21CFR §888.3040) MBI

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K992487	Mitek® Mini QA+ Anchor
K080352	Mitek® Micro QA+ with #3-0, #4-0 Orthocord Anchor/ Mitek Microfix QA+ with #3-0, #4-0 Orthocord Ancho

Device Description:
The JuggerKnot™ Mini Soft Anchors consist of a coreless sleeve structure and suture. The anchors are intended for use in soft tissue fixation by bunching against bone when deployed.

Intended Use / Indications for Use:
The JuggerKnot™ Mini Soft Anchors are intended to be used for soft tissue to bone fixation with indications for use in:

Shoulder
Bankart repair

Foot and Ankle
Midfoot Reconstruction, Hallux valgus reconstruction

Hand and Wrist
Ulnar or lateral collateral ligament reconstruction, Repair/reconstruction of collateral ligaments, flexor and extensor tendon at the PIP (proximal interphalangeal, DIP (distal interphalangeal), and MCP (metacarpal interphalangeal) joints for all digits, Scapholunate ligament reconstruction.

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Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Summary of Technologies:
The technological characteristics (materials, design, sizing and indications) of the JuggerKnot™ Mini Soft Anchors are similar or identical to the predicate devices and other soft tissue fixation devices.

Non-Clinical Testing:
Non-clinical laboratory testing was performed to verify the fixation strength of the JuggerKnot™ Mini Soft Anchors in mechanical pullout testing as compared to the predicate devices. The efficacy of the JuggerKnot™ Mini Soft Anchors was compared to that of the Mitek® Mini QUICKANCHOR® Plus and the Mitek® Microfix QUICKANCHOR® Plus. The test results indicate that the Biomet Sports Medicine JuggerKnot™ Mini Soft Anchors provide equivalent fixation 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
% Ms. Elizabeth Wray
Senior Regulatory Specialist
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581-0587

AUG 19 2011

Re: K110879
Trade/Device Name: JuggerKnot™ Mini Soft Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bond fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: July 22, 2011
Received: July 25, 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. 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 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,

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

Enclosure

K110879 (1/1)

Indications for Use

510(k) Number (if known):_____

Device Name: JuggerKnot™ Mini Soft Anchors

Indications For Use:

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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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