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 Anchors

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.
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.

All trademarks are the property of Biomet, Inc., except for Mitek® and QUICKANCHOR® which are the property of DePuy Mitek / Mitek Products.
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 [link] 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 [link] 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 [link].

Sincerely yours,

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): ____________________________

Device Name: JuggerKnot™ Mini Soft Anchors

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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)

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(510(k) Number) K110879

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