K120509 (1/2)

JUL 26 2012

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Stryker All Suture Anchors
Common Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Proposed Regulatory Class:	Class II
Product Codes:	MBI: Fastener, Fixation, Nondegradable, Soft Tissue
For Information Contact:	Kelly Kucharczyk Regulatory Affairs Associate Howmedica Osteonics Corp. 3201 E. 3rd Ave Denver, CO 80210 Phone: (303) 336-7285; Fax (303) 370-5775 Email: kelly.kucharczyk@stryker.com
Legally Marketed Devices to Which Substantial Equivalence Is Claimed:	K070882 - Stryker PEEK TwinLoop Tac K110145 - Biomet JuggerKnot
Date Prepared:	July 24, 2012

Purpose
Stryker Endoscopy is introducing a family of soft tissue anchors for use in orthopedic applications.

Description
The Stryker All Suture Anchors are soft-tissue fixation devices with a push-in design, provided preloaded on a disposable inserter. They are composed of a sheath structure that contains one or more working sutures. The sheath bunches as the anchor is deployed to fixate in bone.

Intended Use
The Stryker All Suture Anchors are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. See indications below.

Indications

Shoulder: Rotator Cuff repair, Bankart repair, SLAP lesion repair, Biceps tendonesis, Acromio-clavicular separation repair, Deltoid Repair, Capsular shift or capsulolabral repair

Elbow: Biceps Tendon re-attachment, ulnar or radial collateral ligament reconstruction

Hand/Wrist: Scaphulolunate ligament reconstruction, carpal ligament reconstruction, repair/reconstruction of collateral ligaments, repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joint for all digits, digital tendon repair

Foot/Ankle: Lateral stabilization, Medial stabilization, Achilles tendon repair, metatarsal ligament repair, hallux valgus reconstruction, digital tendon transfers, mid-foot reconstruction

Knee: Medial Collateral Ligament repair, Lateral Collateral Ligament repair, Patellar tendon repair, Posterior oblique ligament repair, iliotibial band tendonesis.

Hip: Capsular repair, acetabular labral repair

The Stryker All Suture Anchors are supplied sterile and intended for single use only.

Summary of Technologies
The proposed device is substantially equivalent to other commercially available soft-tissue anchors in regard to intended use, design, materials of construct, performance attributes, and operational principles as a soft tissue anchor. The following devices are examples of predicate systems: Stryker PEEK TwinLoop Tac (marketed by the name - PEEK TwinLoop Anchor) and Biomet JuggerKnot Soft Anchor.

Non-Clinical Testing
Non-clinical bench testing was performed to verify both the insertion strength and fixation strength of the Stryker All Suture Anchors. Through ultimate tensile strength testing and an FEA analysis, the efficacy of the Stryker All Suture Anchors was compared to the predicate devices identified within this premarket notification. The results of these evaluations indicate that the Stryker All Suture Anchors provide statistically equivalent insertion and fixation strength to the predicate devices, and will be functional within the intended use.

Clinical Testing
Clinical testing was not required for this submission.

Conclusion
The Stryker All Anchors are substantially equivalent to the predicate devices identified in this premarket notification.

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

JUL 26 2012

STRYKER
% Ms. Kelly Kucharczyk
Regulatory Affairs Associate
3201 East 3rd Avenue
Denver, Colorado 80206

Re: K120509
Trade/Device Name: Stryker All Suture Anchor(s)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: July 13, 2012
Received: July 16, 2012

Dear Ms. Kucharczyk:

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,

For Mark N. Melkerson

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

Enclosure

K120509 (1/1)

Indications for Use

510(k) Number (if known): _____

Device Name: Stryker All Suture Anchor(s)

Elbow: Biceps Tendon re-attachment, ulnar or radial collateral ligament reconstruction

Shoulder: Rotator Cuff repair, Bankart repair, SLAP lesion repair, Biceps tendonesis, Acromio-clavicular separation repair, Deltoid Repair, Capsular shift or capsulolabral repair

Hand/Wrist: Scaphulolunate ligament reconstruction, carpal ligament reconstruction, repair/reconstruction of collateral ligaments, repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joint for all digits, digital tendon repair

Foot/Ankle: Lateral stabilization, Medial stabilization, Achilles tendon repair, metatarsal ligament repair, hallux valgus reconstruction, digital tendon transfers, mid-foot reconstruction

Knee: Medial Collateral Ligament repair, Lateral Collateral Ligament repair, Patellar tendon repair, Posterior oblique ligament repair, iliotibial band tendonesis.

Hip: Capsular repair, acetabular labral repair

The Stryker All Suture Anchors are intended for single use only.

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

510(k) Number K120509

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