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MAY 16 2007

stryker®
Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date: March 19, 2007

Contact Person:

Erica A. Walters, RAC
Sr. Regulatory Representative
408-754-2078(phone)
408-754-2521 (fax)
erica.walters@stryker.com

Device Name:

Proprietary Name:	Stryker PEEK Zip Suture Anchor
Common and Usual Name:	PEEK Suture Anchor
Classification Name:	Screw, Fastener, Fixation, Nonabsorbable, Bone, Soft Tissue (**Class II**, 21 CFR 888.3040, Product Code MBI, Orthopedics Review Panel)

Predicate Devices:

Stryker 5.0mm BioZip Suture Anchor: # K023192, K041305
Arthrex 5.0mm PEEK Corkscrew FT: #K061665

Device Description and Intended Use:

The Stryker PEEK Zip Suture Anchor is a single-use, soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:

Shoulder:
- Rotator Cuff Repair
- Bankart Repair
- SLAP Lesion Repair
- Acromio-Clavicular Separation Repair
- Capsular Shift/Capsulolabral Reconstruction
- Biceps Tenodesis
- Deltoid Repair.

Knee:
- Extra Capsular Repairs
  - Medial Collateral Ligament
  - Lateral Collateral Ligament
  - Posterior Oblique Ligament
- Illiotibial Band Tenodesis
- Patellar Tendon Repair.

Elbow, Wrist, Hand:
- Scapholunate Ligament Reconstruction
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction
- Biceps Tendon Reattachment.

Foot and Ankle:
- Medial Instability Repair/Reconstruction
- Lateral Instability Repair/Reconstruction
- Achilles Tendon Repair/Reconstruction
- Midfoot Reconstruction
- Hallux Valgus Reconstruction.

Pelvis:
- Bladder Neck Suspension Procedures.

The Stryker PEEK Zip Suture Anchor will be manufactured from PEEK-OPTIMA® (polyetheretherketone), a biocompatible polymer manufactured by Invibio Inc. The screw-in anchor is pre-threaded with non-absorbable braided surgical sutures and pre-assembled on a disposable inserter. The suture will be offered in both non-absorbable USP braided polyester suture (#K953531) and non-absorbable USP braided polyethylene suture (#K033654 and #K040472.). The Stryker PEEK Zip Suture Anchor will be validated to a SAL of 10^{-6} using ethylene oxide. The EtO residuals will be tested according to ISO 10993-7:1995.

Prior to introducing the Stryker PEEK Zip Suture Anchor to market, the device will conform to the following voluntary safety and performance standards: ISO 10993-1, Blue Book Memorandum G95-1, EN 550, EN 556-1, EN 11607-1, EN 11607-2, EN 980, EN 1041, and EN ISO 14971.

The material differences between the Stryker PEEK Zip Suture Anchor and Stryker BioZip Suture Anchor (K023192, K041305) do not affect the safety and efficacy of the product; therefore, the Stryker PEEK Zip Suture Anchor is considered substantially equivalent in performance, intended use, safety, and efficacy to the Stryker BioZip Suture Anchor.

The Stryker PEEK Zip Suture Anchor is considered substantially equivalent in material composition, intended use, safety and efficacy to the Arthrex PEEK Corkscrew FT (K061665).

By: Christine Krueger Date: 19 March 2007

Christine Krueger
Design Engineer
Stryker Endoscopy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Endoscopy
% Erica A. Walters, RAC
Sr. Regulatory Representative
5900 Optical Court
San Jose, California 95138

MAY 16 2007

Re: K070758
Trade/Device Name: Stryker PEEK Zip Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 19, 2007
Received: April 3, 2007

Dear Ms. Walters:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

INDICATIONS FOR USE

Device Name: Stryker PEEK Zip Suture Anchor

510(k) Number if known: K070758

The Stryker PEEK Zip Suture Anchor is a soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:

Shoulder:
- Rotator Cuff Repair
- Bankart Repair
- SLAP Lesion Repair
- Acromio-Clavicular Separation Repair
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  - Lateral Collateral Ligament
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- Achilles Tendon Repair/Reconstruction
- Midfoot Reconstruction
- Hallux Valgus Reconstruction.

Pelvis:
- Bladder Neck Suspension Procedures.

The Stryker PEEK Zip Suture Anchor is intended for single-use only.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchhop

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070758