K033252

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stryker® ENDOSCOPY

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Screw, Fixation, Bone 21 CFR §888.3040, Class II
Common and Usual Name:	Bioabsorbable Interference Screw
Proprietary Name:	Stryker Bioabsorbable Interference Screw System

Predicate Device

Stryker Bioabsorbable Interference Screw System, (#K993166), currently marketed by Stryker Endoscopy (San Jose, CA).

Summary

The Stryker Bioabsorbable Interference Screw System is for use in surgical reconstruction of the anterior cruciate ligament (ACL) deficient knee to provide interference fixation of the various ACL autografts and allografts, including the patella bone-patellar tendon-tibial bone graft complex, the semi-tendinosus tendon graft, the semi-membranosus tendon graft, and the Achilles tendon graft. The Stryker Bioabsorbable Interference Screw System is made as a single unit from an absorbable polymer derived from Poly L-lactic acid (ASTM 4169). This device will be sterilized by Gamma irradiation (EN 552) or Ethylene oxide (EN 550) including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6}. The material, molding process, sterilization process for the line extension is equivalent to the predicate device, the Stryker Bioabsorbable Interference Screw System.

The Stryker Bioabsorbable Interference Screw System is substantially equivalent in material of construction, overall design, intended use, safety, and efficacy to the Stryker Bioabsorbable Interference Screw System (#K993166) currently in commercial distribution. When comparing insertion torque and pullout test results, the line extension device has substantially equivalent performance to the predicate device, and is considered substantially equivalent to the Stryker Bioabsorbable Interference Screw System.

Contact: MS

Date: October 1, 2003

Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
(408) 754-2148

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2003

Ms. Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K033252
Trade Name: Stryker Bioabsorbable ACL Screw – Addition of 12 x 35 mm screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: II
Product Code: HWC, MAI
Dated: October 1, 2003
Received: October 17, 2003

Dear Ms. Murphy:

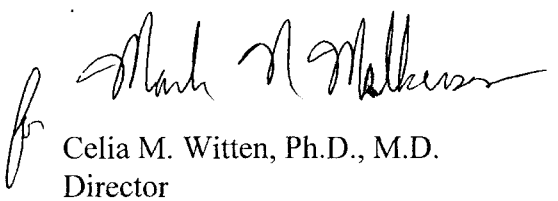
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-__. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

October 1, 2003

510(k) Number if known: K033252

INDICATION FOR USE:

The Stryker Bioabsorbable Interference Screw System is intended for use in the surgical reconstruction of the anterior cruciate ligament (ACL) deficient knee to provide interference fixation of the various ACL autografts and allografts, including the patella bone-patellar tendon-tibial bone graft complex, the semi-tendinosus tendon graft, the semi-membranosus tendon graft, and the Achilles tendon graft. The device is provided sterile and intended for single-use only.

Mark N Milham

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

510(k) Number K033252

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)