510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: September x, 2005

510(k) number: _____ JUL 19 2006

Applicant Information:
KFx Medical
5145 Avenida Encinas
Suite C
Carlsbad, CA 92008

Contact Person
Malcolm Heaven
Phone Number: (619) 270-8475
Fax Number: (760) 602 9252

Device Information:

Trade Name:	KFx Knotless Fixation System and Targeting Grasper
Classification:	Class II
Classification Name:	Bone Anchor; Grasper

Physical Description:
The KFx Knotless Fixation System consists of

- KFx Nail Bone Anchor with two suture leads, mounted to a single use handle
- KFx Suture Lock Bone Screw Anchor mounted to a single use handle
- Optional KFx Targeting Grasper.

Intended Use:

The KFx Knotless Fixation System is intended for the fixation of soft tissue to bone during rotator cuff repair.

Equivalent Device:

The KFx Knotless Fixation System is substantially equivalent to existing suturing devices cleared by the Food and Drug Administration. The Linvatec Super Revo Herculine Suture Anchor (K041713), the Opus Medical Magnum Anchor with Inserter (K041440, K042914), and the Arthrex FASTak Suture Anchor (K960516) devices are examples of substantially equivalent devices with the same intended use, design and technology characteristics requested by KFx Medical, Inc. The intended use of the KFx Knotless Fixation System is substantially equivalent to the intended use of the suturing devices listed above.

Test Results:

Performance

Results of physical bench testing demonstrate that the KFx Knotless Fixation System meets its specifications and does not raise new issues of safety or effectiveness.

Biocompatibility

The materials used in the KFx Knotless Fixation System are biocompatible. The same materials are used in the identified predicates and are also commonly used in similar medical devices.

Summary:

Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

KFx Medical
c/o Ms. Beth Bierman
Morgan Lewis
1111 Pennsylvania Ave., NW
Washington, DC 20004

Re: K061294
Trade/Device Name: KFx Knotless Fixation System and Targeting Grasper
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 8, 2006
Received: May 9, 2006

Dear Ms. Bierman:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

510(k) Number (if known): K061294

Device Name: KFx Knotless Fixation System, Optional KFx Targeting Grasper

Indications for Use:

The KFx Knotless Fixation System and Accessory Targeting Grasper are intended for the fixation of soft tissue to bone during rotator cuff repair.

Prescription Use √ (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)

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

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