Karl Storz
Endoscopy-America, Inc.

600 Corporate Pointe 5th Floor
Culver City, California 90230-7600
Phone 310 338 8100

Toll Free 800 421 0837
Fax 310 410 5527

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

MAR 2 0 2003

Contact: Mario T. Marcelo
Regulatory Affairs Associate

Device Identification: Common Name:
Cannulated Titanium Interference Screw

Trade Name: (optional)
Karl Storz MegaFix-T™ Titanium Interference Screw

Indication: The MegaFix-T™ Titanium Interference Screw is intended for tibial and femoral fixation (primary anchorage) of tendon grafts in anterior and posterior cruciate ligament reconstruction.

Device Description: The MegaFix-T™ is composed of titanium, which is commonly used in medical devices for a wide range of application and has a long history of biocompatibility for human use.

Substantial Equivalence: The MegaFix-T™ is substantially equivalent to the predicate devices since the basic features and intended use are similar. The minor differences between the MegaFix-T™ and the predicate devices raise no new issues of safety and effectiveness, as these minor differences have no effect on the performance, function or intended use of the device.

Signed: _____

Mario T. Marcelo
Regulatory Affairs Associate

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Mr. Mario T. Marcelo
Regulatory Affairs Associate
Karl Storz Endoscopy America, Inc
600 Corporate Pointe 5th Floor
Culver City, CA 90230-7600

Re: K030368
Trade/Device Name: Karl Storz MegaFix-T™ Titanium Interference Screw
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: January 31, 2003
Received: February 4, 2003

Dear Mr. Marcelo:

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) 594-4659. 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,

for Mark N Melkerson

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

Enclosure

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510(k) Number (if known): Not yet assigned

Device Name: Karl Storz MegaFix-T™ Titanium Interference Screw

Indications for Use: The MegaFix-T™ Titanium Interference Screw is intended for tibial and femoral fixation (primary anchorage) of tendon grafts in anterior and posterior cruciate ligament reconstruction.

(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)

for Mark N Milhous

(Division Sign-Off)

(Optional Format 1-2-96)

Division of General, Restorative
and Neurological Devices

510(k) Number K030368

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