K060494

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510(k) Summary of Safety and Effectiveness
MedChannel EasyTAC

Company Name

JUL - 3 2006

MedChannel, LLC
1241 Adams Street #603
Boston, MA 02210

Device Name

Proprietary Name:	MedChannel EasyTac Anchor
Common Name:	Anchor
Classification Name(s):	Implantable Staple
Classification Code(s):	GDW
Classification:	Class II 878.4750

Predicate Devices used for Substantial Equivalence

K032093	PARIEFIX	SOFRADIM PRODUCTION
K043411	RESOFIX	AMI

Intended Use & Indications

The EasyTac Anchor and delivery system is indicated for approximation of soft tissues and fixation of surgical mesh to tissues during laparoscopic surgical procedures such as hernia repair.

Description

The EasyTac Anchor device is an endoscopic or open surgical stapler composed of a disposable delivery instrument and resorbable fixation devices. The EasyTac Anchor Delivery System consists of an ergonomic handle, trigger, locking and unlocking mechanism, rotation knob, shaft containing a cartridge of five to fifteen fixation devices, and retractable hollow needle.

Summary of Standards Achieved

21 CFR § 820	FDA Quality Systems Regulation
ISO 10993:1	Biological evaluation of medical devices -- Part 1: Evaluation and testing
AAMI 11135 Sterilization	Medical Devices - Validation and Routine Control of Ethylene Oxide
ISO 13485	Medical Devices - Quality Management Systems Requirements

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Summary

In summary, the MedChannel EasyTac Anchors are substantially equivalent to legally marketed devices. Quality System Controls assure the device is substantially equivalent to the predicate devices with respect to its performance, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

MedChannel LLC
% Mr. Frederick Tobia
Regulatory Consultant
55 Worcester Street, #3
Boston, Massachusetts 02118

Re: K060494
Trade/Device Name: MedChannel EasyTac Anchor
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: May 30, 2006
Received: June 5, 2006

Dear Mr. Tobia:

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) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Barbara Bruehup
for

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

Enclosure

K060494

Indications for Use

510(k) Number (if known): K060494

Device Name: MedChannel EasyTac Anchor

Indications for Use:

The EasyTac Anchor and delivery system is indicated for approximation of soft tissues and fixation of surgical mesh to tissues during laparoscopic surgical procedures such as hernia repair.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K060494