K061831

510(k) Summary of Safety and Effectiveness
MedChannel HTS System & Accessories

AUG - 7 2006

Company Name

MedChannel, LLC
250 Dorchester Avenue
Boston, MA 02127

Official Contact

Frederick Tobia
Regulatory Consultant

Device Name

Proprietary Name:	MedChannel HTS System
Classification Name(s):	Ultrasonic Pulsed Doppler System
Classification Code(s):	IYN
Classification:	Ultrasonic Pulsed Doppler Systems are Class II Devices

Predicate Devices used for Substantial Equivalence

K951449	Model KM-25	Koven Technologies

Intended Use & Indications

The HTS System is an adjunctive audio vessel landmarking aid for use during hemorrhoidal artery treatment. It is not recommended for fetal or ophthalmic use..

Description

The HTS System is an adjunctive audio vessel landmarking aid for use during hemorrhoidal artery treatment. It is not recommended for fetal or ophthalmic use.. Doppler audio sounds are heard when the transducer is positioned directly over a hemorrhoidal artery. Cessation of Doppler sounds occurs when ligation of the identified vessel has been completed successfully.

Acoustic output values for this transducer are lower than the maximum pre-amendment intensities specified for "Peripheral Vessel" and "Fetal Imaging and Other" applications. There is only one transducer available with this system.

The System includes disposable/single use accessories which can be used to perform the manual ligation of the hemorrhoidal arteries.

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	Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
AAMI 11134	Sterilization of health care products - Requirements for validation and routine control-industrial moist heat sterilization
IEC 60601	Medical Electrical Equipment - Part 1: General Requirements for Safety
UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (NEMA)

Summary

In summary, the MedChannel HTS System is 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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

AUG - 7 2006

Re: K061831
Trade/Device Name: MedChannel HTS System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN
Dated: June 27, 2006
Received: June 29, 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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~K06~~ K061831

Device Name: MedChannel HTS System

Indications for Use:

The HTS System is an adjunctive audio vessel landmarking aid for use during hemorrhoidal artery treatment. It is not recommended for fetal or ophthalmic use.

Prescription Use: X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061831

MedChannel HTS System

Diagnostic Ultrasound Indications for Use Form K061831

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
✓ Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lepanto

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061831