OCT 2 2 2002

K023227

UltraGuide Ltd.

510(k) Summary

Special 510(k)

USG 2000sa

I. Submitter Information

A. Name: UltraGuide Ltd.

B. Address: Yoqne'am, New Industrial Park,
7b Hayezira st., Israel
UltraGuide P.O.B 570
Yokneam Illit 20692

C. Contact Person: Dr. George Myers, 201-727-1703, Fax 201-727-1708

D. Date of preparation: August 15, 2002

II. Device Data

A. Trade Name: USG 2000sa

B. Common Name: Visualization Enhancement System of Interventional Needles under ultrasonic imaging.

C. Classification Name: Locator, Intracorporeal Device, Ultrasonic

III. Legally-marketed predicate devices.

A. UltraGuide 1000, K974432

IV. Description

The UltraGuide USG 2000sa provides visual enhancement of the interventional needle by overlaying the image of the insertion device and its predicted future path on the ultrasound scan image of the internal organs, all displayed on the monitor of a personal computer.

V. Intended Use

The UltraGuide USG 2000sa system is indicated for enhancing the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle or an aspiration needle, and for predicting its future path on a computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system.

The device is intended to be used in clinical applications and for anatomical structures where ultrasound is currently used for visualizing such structures.

VI. Technological characteristics

The device uses magnetic transmitters and receivers, sold under the trade name "PC Birds," to determine the location and orientation of the interventional needle. These devices have been used on medical devices cleared by the FDA. The positions and orientations of the interventional device and the video of the US image, are transmitted to a Personal Computer, which makes the necessary calculations to provide the overlay of the video image and the interventional device.

VII. Testing

A. Non-clinical tests

The USG 2000sa has undergone extensive bench tests for electrical safety and electromagnetic compatibility. The major components (the computer, ultrasound system, and PC Birds) are all commercial devices with published environmental and physical specifications.

B. Clinical Test

Since this system uses the same technology as the predicate device, a clinical test is not necessary.

VIII. Conclusion

The tests show that the UltraGuide USG 2000sa is equivalent to the predicate devices in safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2002

UltraGuide, Ltd.
% Dr. George Myers
Official Correspondent
Medsys, Inc.
377 Route 17 South
HASBROUCK HEIGHTS NJ 07601

Re: K023227
Trade/Device Name: USG 2000sa
Regulation Number: 21 CFR 884.2225
Regulation Name: Obstetric-gynecologic ultrasonic imager
Regulatory Class: II
Product Code: 85 HHJ
Dated: September 25, 2002
Received: September 27, 2002

Dear Dr. Myers:

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

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510(k) Number (if known): K023227

Device Name: USG 2000sa

Indications for Use:

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The device is intended to be used in clinical applications and for anatomical structures where ultrasound is currently used for visualizing such procedures.

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Prescription Use ✓

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023227