UltraGuide Ltd.

510(k) Summary

UltraGuide 1000

I. Submitter Information

A. Name: UltraGuide Ltd.

B. Address: Tirat Hacarmel Industrial Park
POB 2070
Tirat Hacarmel 30200
Israel

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

D. Date of preparation: September 25, 1997

II. Device Data

A. Trade Name: UltraGuide 1000

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. ColorMark Visualization System, K 926351, EchoCath Inc.

B. EchoTip Needles, Cook Manufacturing Co.

C. Regulus Stereotactic system, K935456

D. Civco Needle Guide, K882383

IV. Description

The UltraGuide 1000 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 1000 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 devices.

VI. Technological characteristics

The device uses magnetic transmitters and receivers, sold under the trade name "MiniBirds," to determine the location and orientation of the ultrasound scan head and the interventional needle. These devices have been used on medial devices cleared by the FDA. The positions and orientations of the interventional device, and the video of the ultrasound 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 UltraGuide 1000 has undergone extensive bench tests for electrical safety and electromagnetic compatibility. The major components (the computer, ultrasound system, and MiniBirds) are all commercial devices with published environmental and physical specifications. Physical tests were comparable to that of the ColorMark, which uses a technology which is closer to that of the UltraGuide.

B. Clinical Test

A clinical test was compared on over 50 patients comparing the UltraGuide 1000 and EchoTip needles in an amniocentesis procedure. The UltraGuide 1000 permitted more rapid abd safer placement of the needles and a more rapid procedure. Neither procedure had any adverse events.

VIII. Conclusion

The tests show that the UltraGuide 1000 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

FEB - 9 1998

UltraGuide Ltd.
C/o George H. Myers, Sc.D.
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07601

Re: K974432
UltraGuide 1000
Dated: November 19, 1997
Received: November 24, 1997
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Myers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K974432

Device Name: **UltraGuide 1000**

Indications for Use:

The UltraGuide 1000 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. The enhancement and prediction are presented 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 procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use** ____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

David G. Hegyson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974432