SEP 2 2 2004

K 040213

510(k) SUMMARY

Submitter's name: Microhelix, Inc.
200 Innovation Blvd., State College, PA 16803
The Probe Division of Microhelix, Inc.

Date summary prepared: December 10, 2003

Device name:

Proprietary name:	MHLX7EC Transducer
Common or usual name:	Transducer
Classification name:	Diagnostic ultrasonic transducer, Class II, 892.1570

Legally marketed devices for substantial equivalence comparison:

TETRAD TC-EC7-ACP transducer submitted by TETRAD Corporation under 510(k) #K013849 and the Acuson EC7 transducer, which has been submitted several times by Acuson Corporation as part of complete ultrasound systems, most recently as part of 510(k) #K991805 for the Aspen System.

Description of the device:

The Microhelix MHLX7EC is a replacement ultrasound transducer designed to be used with the Acuson 128XP and Acuson Aspen Systems. It consists of a lens and associated circuitry, a handle which fits around the lens, a cable with strain relief devices on both ends, and a connector to attach the transducer to the ultrasound console.

Intended use of device:

The MHLX7EC Transducer is intended for use in ultrasonic imaging of the human body. The Indications for Use table shows specific uses as abdominal, fetal, transrectal, and transvaginal.

Technological characteristics:

The device features and use parameters of the MHLX7EC are very similar to those of the predicate devices. All of them are ultrasound transducers used on the same ultrasound systems with the same indications for use. No new technology is involved in these devices. All recommend the use of transducer covers and all must be cleaned and disinfected after each use.

Testing conducted:

Electrical, mechanical, and thermal safety testing was conducted on this product and the results included in the 510(k) submission.

Performance testing:

Comparative performance testing was conducted and included in this 510(k). The MHLX7EC and the Acuson EC-7 were tested for acoustic output and were found to be comparable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2004

MicroHelix, Inc.
% Mr. John So
Senior Project Engineer
Conformity Assessment Services
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K040213
Trade Name: MHLX7EC Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: September 3, 2004
Received: September 7, 2004

Dear Mr. So:

We have reviewed your Section 510(k) premarket 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 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson 128 XP System and Acuson Aspen System, as described in your premarket notification:

Transducer Model Number

Microhelix MHLX7EC

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

David A. Lepsow

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

Enclosure(s)

Appendix A:

Diagnostic Ultrasound Indications for Use Form

Microhelix MHLX7EC used on Acuson 128XP

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 B+M; B+PWDB+ CDI; B+PD; B+PWD+C DI	Combined B+M
Ophthalmic										
Fetal		X	X							X
Abdominal		X	X	X		X	X		X	X
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		X	X	X		X	X		X	X
Transvaginal		X	X	X		X	X		X	X
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

Additional Comments: Cardiac is Adult and Pediatric and cardiac analysis. Intraoperative includes abdominal, thoracic and PV, Color Doppler includes Color M, Combined includes B/M, B/Color M, B/PWD, B/Color/PWD. Fetal Doppler not indicated for MHLX7EC used on Acuson 128XP; Abdominal Doppler does not include fetal Doppler for MHLX7EC used on Acuson 128XP

Prescription Use ✓

David R. Legan

(Division Sign-Off)
Division of Reproductive, **Abdominal,**
and Radiological Devices
510(k) Number K040213

Diagnostic Ultrasound Indications for Use Form

Microhelix MHLX7EC used on Acuson Aspen

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 B+M; B+PWDB+ CDI; B+PD; B+PWD+C DI	Combined B+M
Ophthalmic										
Fetal		X	X	X		X	X		X	X
Abdominal		X	X	X		X	X		X	X
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		X	X	X		X	X		X	X
Transvaginal		X	X	X		X	X		X	X
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

Additional Comments: Cardiac is Adult and Pediatric and cardiac analysis. Intraoperative includes abdominal, thoracic and PV, Color Doppler includes Color M, Combined includes B/M, B/Color M, B/PWD, B/Color/PWD.

WARNING – Explosion Hazard: Do not operate the system in the presence of flammable anesthetics.

Prescription Use ✓

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K040213