FEB 10 2009

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. **Submitter's name, address, telephone number, contact person:**

Company Information:

Humanscan Company Ltd.
302 Sinha APT, Factory Sinha Estate #672
Sunggok-dong, Kyunggi-do, Korea 5Ra 301
Contact: Sung Min Rhim, President & CEO

Submitter:

Gary J. Allsebrook, Consultant
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116
Telephone: (510) 388-5001
Fax: (510) 276-2648
Email regman10@comcast.net
Prepared February 9, 2009

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:
Diagnostic Ultrasound System and Accessories
Proprietary Name:
Humanscan M5S-D Transducer

Classification Names:	CFR Number	Product Code
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3. Identification of the predicate or legally marketed device:

The device is identical to the GE, Vivid E9, M5S-D transducer and is, in fact, manufactured for GE by Humanscan Company, Ltd.

4, Device Description:

The Cardiac Ultrasound Transducer (**M5S-D)** is a matrix array probe with 192 elements for GE's ultrasound diagnostic system, Vivid E 9.

5. Intended Use(s):

When used with the GE Vivid E9 Ultrasound System, the Humanscan M5S-D is a phased array ultrasound transducer and is indicated primarily for ultrasonic evaluation of cardiology conditions and also for evaluation of fetal/obstetrics, abdominal, pediatric, adult cephalic and urology/prostate use.

6. Non-clinical tests:

The Humanscan M5S-D was evaluated, by GE, for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

The limits are the same as the predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HUMANSCAN Company Ltd.
% Mr. Gary Allsebrook
Consultant
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 93478-1116

FEB 10 2009

Re: K083824
Trade/Device Name: Humanscan M5S-D Ultrasound Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: December 18, 2008
Received: December 24, 2008

Dear Mr. Allsebrook:

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 Humanscan M5S-D Ultrasound Transducer, as described in your premarket notification:

Transducer Model Number

M5S-D

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 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 (240) 276-0120. 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

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K083824

Device Name: Humanscan M5S-D Ultrasound Transducer

Indications For Use:

The Humanscan M5S-D is phased array ultrasound transducer, for the GE Vivid E9 Ultrasound System, and indicated primarily for ultrasonic evaluation of cardiology conditions. It is also indicated for evaluation of fetal/obstetrics, abdominal, pediatric, adult cephalic, and urology/prostate use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083824

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Humanscan M5S-D Transducer for use with GE Vivid E9 Ultrasound System

510(k) No.: 083824

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

Clinical Application	Mode of Operation (*includes simultaneous B-mode)										
Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic imaging	Coded Plus	Other (Spec.)
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac [3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N= new indication; P= previously cleared by FDA in K08921; E= added under Appendix E

Note 2: Small Organ includes breast, testes and thyroid

Note 3: Cardiac is Adult and Pediatric.

Note 4: Other Use includes Urology/Prostate

*Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083824