DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2005

Chison Medical Imaging Co., Ltd.
% Mr. Tamas Borsai
Division Manager, Medical Division and
Program Manager, Third Party Review Program
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K050167
Trade Name: CHISON 600M
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: January 24, 2005
Received: January 26, 2005

Dear Mr. Borsai:

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 CHISON 600M, as described in your premarket notification:

Transducer Model Number

Convex Array C60
Linear Array L700
Micro-convex Array C14

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

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

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(s)

Attachment 4.3.1

Diagnostic Ultrasound System Indications for Use Form

Device Name: CHISON 600M

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

N=new indication

Additional Comment: Small organs include :thyroid, parathyroid, parotid, submaxillary gland,and Breast

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050167

Prescription Use ✓

CHISON MEDICAL IMAGING CO., LTD.

510(k) Submission Application

Attachment 4.3.2

CHISON 600M Ultrasound Imaging System

Scanhead Indications for Use Form

Device Name : Convex Array C60

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

N=new indication

Abdomen include: Kindey, Liver, Pancreas, Gall bladder, Uterus etc.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050167

Prescription Use ✓

Attachment 4.3.3

CHISON 600M Ultrasound Imaging System

Scanhead Indications for Use Form

Device Name :Linear Array L700

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

N=new indication

Additional Comments: Small organs include :thyroid, parathyroid, parotid, submaxillary gland, and breast

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K050167

Prescription Use ✓

Attachment 4.3.4

CHISON 600M Ultrasound Imaging System

Scanhead Indications for Use Form

Device Name : Micro-convex Array C14

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

N=new indication

Additional Comments:_____

_____

_____

_____

_____

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K050167

Prescription Use ✓