K090229

PREMARKET NOTIFICATION [510(k)] Summary

MAR 13 2009

Company Name: Chang Gung Medical Supplies & Equipment Corp.
5F., No. 201-36, Dunhua N.Rd. Songshan District
Taipei, TAIWAN 10508

U.S. Agent: Bob Leiker
Leiker Regulatory & Quality Consulting
7263 Cronin Circle Dublin, CA 94568
Telephone: (925) 556-1302

Device Name: CGMC Diagnostic Doppler Ultrasound System OPUS 5000 with
CGMC CLA35 Curved Linear Array 4-8MHz,
CGMC LA75 Linear Array 5-10MHz,
CGMC PA25 Phase Array 2-4MHz, and
CGMC TV65 Transvaginal Micro-Curved Linear Array 4-8MHz.

Classification Name: Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Diagnostic Ultrasound Transducer 21 CFR *892.1570,* Product Code 90-ITX

Predicate Device:
The SonoScape Ultrasound System SSI-1000 (K042369) is of a comparable and substantially equivalent type. It has the same technological characteristics, key safety and effectiveness features, physical design, and has the same intended uses and basic operating modes as the predicate device.

General Device Description:
The CGMC OPUS 5000 diagnostic doppler ultrasound system is a compact and portable diagnostic ultrasound device,have integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The user interface includes a specialized control keyboard and color 15-inch LCD display. The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

The major features of the CGMC OPUS 5000:

- 64 Channel all digital beam former
- Progressive dynamic receive focusing
- Wide band all digital demodulation
- Native frequency digital scan converter
- OPUS 5000 can be hand carried for portable use
- Remote access image management through LAN port
- USB2.0 flash drive for image transport and software upgrade
- Supports 2D B-mode, M-mode, Harmonic Image, Color, Power Doppler, Pulse wave Doppler, and CW.

Intended Use:
The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen;Pediatric;Small Organ(breast,tests,thyroid);heart soft tissue;Peripheral Vascular;Musculo-skeletal(conventional);Ob/Gyn and Urology.

Technological Characteristics:

Display Modes	Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time.
Measurements	Distance; area; circumference; calipers; velocity, PI, RI. Cardiac and Vascular package.
Operating Controls	• TGC 8 slider, +/- 24dB • Depth Range: 3 to 24 cm • Image sector size: 32 lines to full B (256 lines) • Image Sector position: Steering within full maximum • B orientation flip: L/R key with marking on the screen • B Dynamic range control: preset 5 curves over 50-90 dB • Gray Scale Control: 8 Settings • Focal Number: 16 focal zone setting • B persistence: 30-90% recursive • Image Processing: Smoothing, edge enhancement • PW sweeping speed 2,4,8 sec over display. • PW Wall filter setting: 16 settings, 0.25 to 20% of PRF • PW sample volume: 0.5 to 10mm with 0.5mm step size. • PW/B update: with UPDATE key • PW cursor steering: Steer soft key • PW angle correction: 0 to 70 degree user control • PW trace: Peak, Mean • PW spectrum dynamic range: 5 preset curve over 15-48 dB • Spectrum baseline shift and invert • Color ROI setting: trackball and set key to control size and • Color steering on flat probe: +, 0, - • Color Wall Filter: Color wall filter with 16 selection, 0.25-20% • Color & B priority: C-B priority soft menu • Color Packet size: preset per Exam range from 8 to 12 • Color spatial filter: preset per Exam, horizontal, vertical, off • Zoom factor: 1 to 10 continuously • Freeze control: Toggling freeze key • Cine control: step, play backward, play continuously
Acoustic Output	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS /ITIB/TIC: 0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm 2max

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2009

Chang Gung Medical Supplies & Equipment Corp.
% Mr. Bob Leiker
Owner & Manager
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
DUBLIN CA 94568

Re: K090229
Trade/Device Name: CGMC OPUS 5000 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 28, 2009
Received: January 30, 2009

Dear Mr. Leiker:

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 CGMC OPUS 5000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

PA25 2.5 MHz Phased Array
LA75 7.5 MHz Linear Array
CLA35 3.5 MHz Curved Linear Array
TV65 6.5 MHz Trans-Vaginal/Trans-Rectal Micro-Curved Linear Array

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.

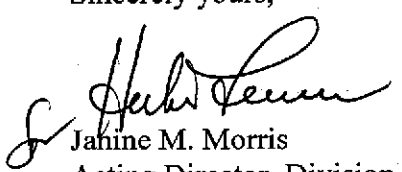
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K090229

Device Name: CGMC OPUS 5000 Diagnostic Ultrasound System

Indications For Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen; Cardiac, Small Organ (breast, testes, thyroid); heart soft tissue; Peripheral Vascular; Musculo-skeletal (conventional); OB/Gyn and Urology.

Prescription Use √ 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 K090229

Diagnostic Ultrasound Indications For Use Format

System: CGMC OPUS 5000
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	Note 1	N
	Small Organ (breast, thyroid, testes)	N	N	N		N	N	Note 1	N
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	N
	Trans-vaginal	N	N	N		N	N	Note 1	N
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use (Per 21 CFR 801.109)
Section 1.3

Indications For Use

510(k) Number K090229

Diagnostic Ultrasound Indications For Use Format

System: CGMC OPUS 5000
Transducer: PA25 2.5 MHz Phased Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090229

Prescription Use (Per 21 CFR 801.109)

Section 1.3 Indications For Use

Diagnostic Ultrasound Indications For Use Format

System: CGMC OPUS 5000
Transducer: LA75 7.5 MHz Linear Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)	N	N	N		N	N	Note 1	N
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090229

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: CGMC OPUS 5000
Transducer: CLA35 3.5 MHz Curved Linear Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

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Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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510(k) Number K090229

Prescription Use (Per 21 CFR 801.109)

Section 1.3 Indications For Use

Diagnostic Ultrasound Indications For Use Format

System: CGMC OPUS 5000
Transducer: TV65 6.5 MHz Trans-Vaginal/Trans-Rectal Micro-Curved Linear Array Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	N
	Trans-vaginal	N	N	N		N	N	Note 1	N
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

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Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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