510(k) SUMMARY

1. Submitter Information

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Date Submitted: 9/6/2013

2. Contact Information

Name: Jimmy Wu

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3. Device Information

Common Name: Colposcope (HEX)

CFR Section: 21 CFR 884.1630

Product Classification: Class II

Classification Panel: Obstetrics/Gynecology

Product Code: HEX

Trade Name: GC-3000E Digital Colposcope System

4. Predicate Device

Manufacturer: Goldway

Trade name: SLC-2000 Digital Video Colposcope Imaging System

510(k) Number: K021153

5. Device Description:

GC-3000E is a digital colposcope intended to provide magnified viewing of the vagina, cervix and external genitalia. GC-3000E is used to diagnose abnormalities and select areas for biopsy. GC-3000E acquires and displays high-resolution still and sequentially captured images and videos.

GC-3000E offers non-patient contact, fully digital and high-resolution imaging of the cervix. The field of view is illuminated by circular LED group light source; a high-resolution color CCD camera provides crisp magnified color images. The images can be viewed on a commercially available color monitor.

Components: Digital Camera, Vertical Stand

6. Intended Use

The GC-3000E Digital Colposcope is intended for the magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and select areas for biopsy. The image can be viewed on a color screen or computer monitor and printed on a color printer. The device is intended to be used in hospitals and clinics.

7. Comparison to Predicate Device

Specification	SLC-2000A (GW)	GC-3000E	Discussion
Standard Configuration	Digital Camera, Stand	Digital Camera, Stand	
Minimum monitor resolution specification	1024 * 768	1024 * 768	
Light module	Loop group LED light	Loop group LED light	
Light source	main: white light	main: white light	
White light color rendering	75 or below	85 or above	High "color rendering" allows an object's color to appear more natural. GC-3000E has higher "color rendering" performance than SLC-2000A, and it provides better performance. The difference does not affect GC-3000E's effectiveness and safety.

Illuminance	2200 Lx at working distance 300 mm	2046 Lx at working distance 300 mm	GC-3000E's illuminance at working distance of 300mm is slightly lower than SLC-2000A's illuminance. Both devices, at working distance of 300mm, provide sufficient light, ≥ 2000Lux, for performance of visual tasks of low contrast and small size for prolonged periods of time. The difference does not affect GC-3000E's effectiveness and safety.
Illuminance range	≥ φ60mm, at working distance 200mm	≥ φ60mm, at working distance 200mm	
Light source lifetime	≥ 10,000 hours	≥ 10,000 hours	
MTBF	≤50,000h	~38,000h	GC-3000E will be turned on 6 hours per day, 250 days per year, totally 1,500 hours per year. Therefore, GC-3000E's MTBF in years is between 25 & 26 years. Although GC-3000E's MTBF may be less than Predicate device's MTBF (≤ 50,000 hours), it will not affect GC-3000E's safety & effectiveness because both MTBFs are longer than digital colposcope's normal service lives, ≤ 10 years.
System resolution	≥ 470 TVL	≥ 500 TVL	GC-3000E's system resolution is higher than SLC-2000A's system resolution, and it performs better visually. The difference does not affect GC-3000E's effectiveness and safety.
Image geometric distortion	2.6%	1.8%	GC-3000E's has lower image distortion, and provides better visual result. The difference does not affect GC-3000E's effectiveness and safety.
Magnification	Optical: 1~36X Digital Magnification: 1~40X	Optical: 1~36X Digital Magnification: 1~40X	

Field of View	52° or at minimum magnification ≥ϕ60mm & at maximum magnification ≥ϕ10mm。	52° or at minimum magnification ≥ϕ60mm & at maximum magnification ≥ϕ10mm。	
Depth of field	• At minimum magnification ≥120mm; • At maximum magnification ≥5mm	At minimum magnification ≥120mm; At maximum magnification ≥5mm	
Focus mode	**Electronic control:** • Auto focus only	**Electronic control:** Manual and auto focus	GC-3000E's focus control mode provides more control capability. It does not affect GC-3000E's visual quality. The difference does not affect GC-3000E's effectiveness and safety.
Multi-spectral light imaging	No	No	
Electronic filter	green filter （3 grade）	green filter （3 grade）	
Magnification and timing display	Yes	yes	
Freeze function	YES	YES	
Stand type	vertical	vertical	
Video output	S-Video, Video	S-Video, Video	
External power source	Voltage：100～240VAC Frequency：50/60Hz Input power：Maximum 500VA Fuse：Input:5A，Output: 2A	Voltage：100～240VAC Frequency：50/60Hz Input power：Maximum 500VA Fuse：Input:5A，Output: 2A	
Conformance to industrial standards	IEC 60601-1	IEC 60601-1, IEC 60601-1-2:2007, ISO 8600-3, ISO 8600-5	

8. Nonclinical Tests

GC-3000E colposcope meets following performance standards:

- ISO 8600-3, 1st edition 1997
- ISO 8600-5, 1st edition 2005
- IEC 60601-1, 2nd edition 1988 (A1:1991 + A2:1995)
- IEC 60601-1-2, 3rd edition 2007

Other nonclinical tests on thermal safety, image quality and device reliability were met:

- Thermal Safety Test
- Image Distortion Test
- Reliability Prediction of Electronic Equipment Standard, 1991

9. Conclusion

The GC-3000E colposcope has the same intended use and substantially equivalent technological characteristics as the predicate devices. The non-clinical testing which included the use of recognized performance standards demonstrates that the GC-3000E colposcope is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

Shenzhen GoldCare Meditech Co., Ltd.
% Jimmy Wu
Associate
Lee & Xiao Attorneys
2600 Mission Street, Suite 100
San Marino, CA 91108

Re: K122311
Trade/Device Name: GC-3000E Digital Colposcope System
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated (Date on orig SE ltr): September 6, 2013
Received (Date on orig SE ltr): September 10, 2013

Dear Jimmy Wu,

This letter corrects our substantially equivalent letter of September 18, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K122311

Device Name: GC-3000E Digital Colposcope System

Indications for Use:

The GC-3000E Digital Colposcope is intended for the magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and select areas for biopsy. The image can be viewed on a color screen or computer monitor and printed on a color printer. The device is intended to be used in hospitals and clinics.

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)

Herbert P. Lerner -S

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