



Food and Drug Administration
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September 14, 2016

Xuzhou Kernel Medical Equipment Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K160341
Trade/Device Name: Colposcope System
Models: KN-2200/ KN-2200A/ KN-2200I/ KN-2200I(H)/
KN-2200B/ KN-2200BI
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: August 8, 2016
Received: August 18, 2016

Dear Diana Hong:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

For Division

Douglas Silverstein -S
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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

Indications for Use

510(k) Number (if known)

K160341

Device Name

Colposcope System

Models: KN-2200/ KN-2200A/ KN-2200I/ KN-2200I(H)/ KN-2200B/ KN-2200BI

Indications for Use (Describe)

The Colposcope System is intended for magnified viewing of the vagina, cervix and external genitalia in order to assist doctors in diagnosing abnormalities and select areas for biopsy. It is intended to be used only by trained and qualified personnel in hospitals, clinics and private offices, and not intended for home use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K160341

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 09/02/2016
2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person) Ms. Jing Cheng (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Colposcope System
Common Name: Video Colposcope and Binocular Colposcope
Models: KN-2200/ KN-2200A/ KN-2200I/ KN-2200I(H)/ KN-2200B/ KN-2200BI

Regulatory Information Classification Name: Colposcope
Regulatory Classification: Class II
Product Code: HEX, colposcope (and colpomicroscope)
Regulation Number: 21CFR 884.1630
Review Panel: Obstetrics/Gynecology

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K021153
Product Name: Goldway SLC-2000 Digital Video Colposcope Imaging System
Model Name: SLC-2000A

Predicate Device 2
510(k) Number: K070845
Product Name: Colposcope COLPO-99/99 Plus
Model Name: COLPO-99 Plus

Predicate Device 3
510(k) Number: K140754
Product Name: Leisegang Colposcope Systems
Model Name: 3ML

6. Device Description

The Colposcope System is intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The Colposcope System has two kinds of colposcopes, a video colposcope and a binocular colposcope.

The video colposcope system is a non-patient contacting image capture device (CCD color camera) with a digital magnification of up to x16, working distance supporting 200mm~400mm, and a green filtered light source mounted on a vertical stand, swing arm stand or trolley. Tissue is magnified and viewed directly via the LCD screen attached to the capture device or on the commercially available color monitor. The video colposcope system has four models, including KN-2200, KN-2200A, KN-2200I and KN-2200I(H).

The binocular colposcope system is designed based on an optical colposcope. Its imaging system consists of optical imaging and CCD imaging. It permits viewing of the tissues of the vagina, cervix and external genitalia by a telescopic system and the CCD camera captures digital images. The binocular colposcope system has two models, including KN-2200B and KN-2200BI. The two models have the same binoculars, CCD camera, cables except for the light source size and the stand type.

Both video colposcope system and binocular colposcope come with image management software, which is provided on a CD-ROM. The image management software allows the viewer to view, compare, record and print the image by series peripheral units, such as computer, monitor and printer.

7. Indications for Use

The Colposcope System is intended for magnified viewing of the vagina, cervix and external genitalia in order to assist doctors in diagnosing abnormalities and select areas for biopsy. It is intended to be used only by trained and qualified personnel in hospitals, clinics and private offices, and not intended for home use.

8. Predicate Comparison

Table 1 Comparison of Technology Characteristics between the subject Video Colposcope System and predicate device 1

Item	Colposcope System	Predicate Device 1 K021153
Model	KN-2200/2200A/KN2200I/KN-2200I(H)	SLC-22000A
Intended environment	Hospitals, clinics and doctor's office	Hospitals, clinics and doctor's office
Intended Use	The Colposcope System is intended for magnified viewing of the vagina, cervix and external genitalia in order to assist doctors in diagnosing abnormalities and select areas for biopsy. It is intended to be used only by trained and qualified personnel in hospitals, clinics and private offices, and not intended for home use.	The Goldway Digital Video Colposcope System is intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The image system is intended to provide documentation of the image in the field of view of the colposcope. The image can be viewed on a color screen, printed on a color printer or archived for storage and subsequent retrieval. The device is intended for use in hospitals and clinics.

Configuration	Digital camera, stand	Digital camera, stand
Light module	Loop group LED light	Loop group LED light
Working distance	200mm~400mm	150mm~350mm
Illumination	≥1200Lx at working distance 200mm to 400mm	2200Lx at working distance 200mm to 400mm
Illumination range	≥φ60mm, at working distance 200mm	≥φ60mm, at working distance 200mm
Light source lifetime	≥ 10,000 hours	≥ 10,000 hours
MTBF	59817 hours (KN-2200) 26985 hours (KN-2200A) 19778 hours (KN-2200I) 37301 hours (KN-2200I(H))	≤ 50, 000 h
System resolution	≥ 700 TVL (KN-2200/2200A) ≥ 550 TVL (KN-2200I) ≥ 1000 TVL (KN-2200I(H))	≥ 470 TVL
Image geometric distortion	≤2.5%	2.6%
Focus mode	Electronic control: Manual and auto focus	Electronic control: Auto focus only
Multi-spectral light imaging	No	No
Electronic filter	Green filter	Green filter
Freeze function	Yes	Yes
Biocompatibility	No patient contacting material	No patient contacting material

The proposed video colposcope system has the same intended use but different technological characteristics compared to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness.

Table 2 Comparison of Technology Characteristics between subject Binocular Colposcope System and predicate devices 2 and 3

Item	Colposcope System	Predicate Device 2 K070845	Predicate device 3 K140754
Model	KN-2200B/2200BI	Colpo-99 Plus	3ML
Product Code	HEX	HEX	HEX
Regulation Number	CFR 884.1630	CFR 884.1630	CFR 884.1630
Intended environment	Hospitals, clinics and doctor's office	Hospitals, clinics and doctor's office	Hospitals, clinics and doctor's office
Intended Use	The Colposcope System is intended for magnified viewing of the vagina, cervix and external genitalia in order to assist doctors in diagnosing abnormalities and select areas for biopsy. It is intended to be used only by trained and qualified personnel in hospitals, clinics and private offices, and not intended for home use.	The Sounmed Colposcope COLPO-99 is intended to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select area for biopsy.	The Cooper Surgical Leisegang Colposcope Systems are intended for the magnified viewing of the tissues of the vagina, cervix, and external genitalia in order to assist doctors in diagnosing abnormalities such as lesions or cancer, and selecting areas for biopsy. The

			images from Cooper Surgical Leisegang Colposcopes may be viewed directly and/or on a color monitor (if so equipped). Cooper Surgical Leisegang Colposcopes are intended for use in hospitals, clinics, and doctor's offices.
Configuration	Binoculars, Digital Camera; Stand;	Binoculars, Stand;	Binoculars, Digital Camera; Stand;
Light source	LED light	Halogen lamp	LED light
Binoculars	Inclined, f ^r =160mm	Straight, f ^r =160mm	Straight or inclined
Objective	f ^r =300mm	f ^r =300mm	Unknown
Eyepiece magnification	12.5x with diopter adjustment	12.5x with diopter adjustment	Unknown
Diopter adjustment	-5D to +5 D	-5D to +5 D	-7D to +7 D
5 step magnification	0.4x, 0.6x, 1x, 1.6x, 2.5x	0.4x, 0.6x, 1x, 1.6x, 2.5x	Unknown
MTBF	41445 hours	Unknown	Unknown
Illumination	≥30,000 lx	80,000lx	23,000~35,000lx
Image geometric distortion	≤2.5%	Unknown	Less than 7%
Focus mode	Manual	Manual	Manual
Electronic filter	Green filter	Green filter	Green filter
Biocompatibility	No patient contacting material	No patient contacting material	No patient contacting material

The proposed binocular colposcope system has the same intended use but different technological characteristics compared to the predicate devices. The differences in technological characteristics do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Tests

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is substantially equivalent to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance, including the US National Differences
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- ISO 8600-3:1997 Optics and optical instruments--Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-5:2005 Optics and photonics-Medical endoscopes and endotherapy devices. Part 5: Determination of optical resolution of rigid endoscopes with optics

Other non-clinical tests were conducted to show that the device met its performance specifications. The following tests were conducted:

- Illuminance Test
- Image Distortion Test
- System Resolution test

10. Conclusions

Based on the comparison and analysis above, the proposed device is substantially equivalent to the predicate devices.