DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 1, 2015

Edan Instruments, Inc.
% Doug Worth
Sr. Director, US Regulatory and Quality Affairs
Edan Medical USA, Inc.
1200 Crossman Ave, Suite 200
Sunnyvale, CA 94086

Re: K151878
Trade/Device Name: Video Colposcope, Models C3A, C6A
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: October 21, 2015
Received: October 26, 2015

Dear Doug Worth,

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151878

Device Name
Video Colposcope, models C3A, C6A

Indications for Use *(Describe)*
The C3A, C6A video colposcope is intended for gynecological examination. It provides magnified visualization of the vagina, cervix and external genitalia, which can help diagnose 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 or to touch the patient.

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.

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510（K） Summary

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

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Date prepared:
November 30, 2015

Device Identification:
Trade name: Video Colposcope, models C3A, C6A
Common name: Colposcope
Regulation No: 21 CFR 884.1630, Colposcope
Regulatory Class: II
Product Code: HEX – Colposcope

Predicate Device:
Shenzhen Goldway Medical Electronics Co., Ltd,
SLC-2000 Digital Video Colposcope Imaging System
(K021153)

Cleared – February 10, 2003

Device Description:
The Edan video colposcope, including models C3A and C6A, consists of the camera module (CCD color camera), stand (vertical or swing arm stand), video capture box, foot switch, and video colposcope software. The Edan video colposcope is a non-patient contacting medical device.

The C3A, C6A video colposcope is a digital imaging equipment that works as follows: The loop group LED light illumines the target, and the CCD camera takes images of the target. The images are converted into video signals, which are then captured and transmitted to a commercially available computer or monitor. The video colposcope software implements the functions of

displaying images, capturing images or taking videos, storing and managing images and providing reports.

Indications for Use: The C3A, C6A video colposcope is intended for gynecological examination. It provides magnified visualization of the vagina, cervix and external genitalia, which can help diagnose 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 or to touch the patient.

Predicate Device Comparison

The subject device and the predicate device (K021153) have the same fundamental technology and similar technological characteristics, detailed in the table below:

Comparison Items	**SLC-2000A(GW)**	**C3A&C6A**	**Comparison of C3A, C6A with SLC-2000A**
Manufacturer/K#	Goldway/K021153	EDAN	N/A
Indications For Use			
Indications for Use	The Goldway Digital Video Colposcope Imaging 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 to be used in Hospitals and clinics.	The C3A, C6A video colposcope is intended for gynecological examination. It provides magnified visualization of the vagina, cervix and external genitalia, which can help diagnose 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 or to touch the patient.	Different
Power Supply			
Voltage	100 V-240 V~	100 V-240 V~	Same
Frequency	50 Hz/60 Hz	50 Hz/60 Hz	Same

Input power (Maximum)	500 VA	48 VA	Different
Specifications			
Standard Configuration	Digital CCD camera, Stand	Digital CCD camera, Stand	Same
Light module	Double loop group LED light	Single loop group LED light (C3A) Double loop group LED light (C6A)	Different
Light source	White LED light	White LED light	Same
Illumination	2200 lux at working distance 300 mm	1600 lux at working distance 300 mm (C3A) 3000 lux at working distance 300 mm (C6A)	Different
Illumination range	≥φ60 mm at working distance 200 mm	≥φ60 mm at working distance 200 mm	Same
Light source lifetime	≥10,000 hours	≥10,000 hours	Same
System resolution	≥470 TVL	≥500 TVL	Different
Space resolution	Not available	≥10 lpm	Different
Image geometric distortion	<2.6%	<3%	Different
Magnification	1 ~ 40X	1 ~ 28X (C3A) 1 ~ 36X (C6A)	Different
Operation Distance:	200 mm-300 mm	200 mm-300 mm	Same
Field of view	At minimum magnification 52°or ≥φ60 mm At maximum magnification ≥φ10 mm	3X: ≥φ80 mm OR ≥16.5° 18X:≥φ12 mm OR ≥2.5°	Different
Depth of field:	1X: ≥ 120 mm 40X: ≥ 5 mm	6X: ≥120 mm 18X: ≥6 mm	Different
Focus mode	Electronic control: Auto focus only	Electronic control: Manual and auto focus	Different
Electronic Filter	Green filter (3 grades)	Green filter (3 grades)	Same
Magnification and timing display	YES	YES	Same
Freeze function	YES	YES	Same
Stand type	Vertical	Vertical, swing arm (optional)	Different
Video Output	S-Video, Video	S-Video	Different
MBTF	≤ 50,000h	≤ 48,956h	Different

Standards Compliance	IEC60601-1	IEC 60601-1: 2005, IEC 60601-1-2: 2007, ISO 8600-3, ISO 8600-5	Different

The technological characteristics of the C3A, C6A video colposcope are comparable to the predicate device.

Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the C3A, C6A video colposcope. The system complies with the IEC 60601-1:2005/A1: 2012 and standards for safety and the IEC 60601-1-2: 2007 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Bench Testing

The most important performance specification is about the features associated with imaging, testing conducted to show the effectiveness of the subject device include:

- ISO 8600-3: 2003 Optics and photonics —Medical endoscopes and endotherapy devices — 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.
- Thermal Testing
- Image Geometric Distortion Testing

Conclusion

The results of the testing demonstrate that the C3A, C6A video colposcope is as safe and effective as the predicate device and supports a determination of substantial equivalence.