September 21, 2018

Hadleigh Health Technologies, LLC
% Spencer Walker
Director of Regulatory Affairs
University of Utah
Center for Medical Innovation
10 North 1900 East, EHSL Rm. 22B
Salt Lake City, Utah 84112

Re: K181034
Trade/Device Name: Pocket Colposcope System
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: Class II
Product Code: HEX
Dated: August 15, 2018
Received: August 17, 2018

Dear Spencer Walker:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181034

Device Name
Pocket Colposcope System

Indications for Use *(Describe)*
The Pocket Colposcope is a digital video colposcope intended for gynecological examination. It provides a portable means of magnified visualization of the tissues of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The image system is intended to provide documentation of the image in the field of view of the colposcope. The Pocket Colposcope System is intended to be inserted into the vagina via a speculum by trained medical personnel in hospitals, clinics, and private offices, and is 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.

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510(k) Summary – K181034

Submitter: Hadleigh Health Technologies, LLC
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San Rafael, CA 94901

Contact Person: Spencer Walker, MSc
Director Regulatory Affairs
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Salt Lake City, UT 84112 (801)
581-5080

Date Prepared: September 20, 2018

Trade Name: Pocket Colposcope System

Common Name: Colposcope

Classification: Colposcope, 21 CFR §884.1630
Product Code HEX, Colposcope (and colpomicroscope)
Class II

Predicate Device(s):

K151878 – Edan Instruments, Video Colposcope, models C3A, C6A

The predicate device has not been subject to a design-related recall.

Device Description:

The Pocket Colposcope is a reusable, high-definition video colposcope intended to be used in a hospital / clinical environment for examination of the tissues of the vagina, cervix and external female genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The Pocket Colposcope can be used outside of the body to capture images of the vagina and external genitalia or can be inserted through a vaginal speculum to capture images of the cervix and surrounding tissue. The Pocket Colposcope it is not intended to come into direct contact with the body.

The Pocket Colposcope utilizes a ring or single loop of LED lights to illuminate the target tissue. The digital color image generated by the Pocket Colposcope is intended to be used to aid in diagnosing abnormalities and selecting areas for biopsy. Users can switch between the white and green light illumination and zoom in or out to capture images at different working distances.

The Pocket Colposcope has a 5 MP CMOS camera with a 0° angled lens. The Pocket Colposcope uses a computer-based software program to display the camera output on a computer screen and to capture images. Together, the Pocket Colposcope and the software

comprise the Pocket Colposcope System.

Pocket Colposcope Features
The Pocket Colposcope Device is used like other colposcopes, and has the following features:

- Camera & Lens: 0° lens, 5 Mega Pixel CMOS sensor
- Light Source: Four (4) white and four (4) green LEDs arranged in a ring at the probe tip
- Rigid Shaft (Probe): 13.7 cm length, 1.8 cm diameter at the distal tip
- Rigid Handle: 13 cm length
- Zoom, light, and image capture controls
- USB type A video cable attached to scope handle to connect to a computer.
- Packaged non-sterile and designed for reuse after cleaning and High Level Disinfection,
- High-definition video output

Indications For Use:
The Pocket Colposcope is a digital video colposcope intended for gynecological examination. It provides a portable means of magnified visualization of the tissues of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The image system is intended to provide documentation of the image in the field of view of the colposcope. The Pocket Colposcope System is intended to be inserted into the vagina via a speculum by trained medical personnel in hospitals, clinics, and private offices, and is not intended for home use.

Comparison of Technological Characteristics:
The following table compares the technological characteristics of the subject and predicate device:

Table 1: Substantial Equivalence Table Comparison		
	Subject Device	**K151878**
Device Name	Pocket Colposcope	EDAN C3, C6A Colposcope
Indications for use	The Pocket Colposcope is a digital video colposcope intended for gynecological examination. It provides a portable means of magnified visualization of the tissues of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The image system is intended to provide documentation of the image in the field of view of the colposcope. The Pocket Colposcope System is intended to be inserted into the vagina via a speculum by trained medical personnel in hospitals, clinics, and private offices, and is not intended for home 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.
Class	21 CFR §884.1630	Same

Table 1: Substantial Equivalence Table Comparison		
	Subject Device	**K151878**
	Product code: HEX Class II	
Multiple Use	Yes	Yes
Prescription (Rx Only)	Yes	Yes
Anatomical site	Cervix, vagina, and external genitalia	Same
Where used	Hospitals and clinics	Same
Device Design		
Device Design	 	
Standard Config.	Digital CMOS camera used without stand	Digital CCD camera with Stand, may be used without the stand.
External Power Source	Voltage: 5 V, Frequency: DC Input power: USB 5V	Voltage: 100 - 240VAC, Frequency: 50/60Hz, Input power: Maximum 48VA
Materials	Housing - ABS Plastic Lens–PMMA	Housing - ABS Plastic Lens - Glass
Fundament. Scientific Technology	The camera has optics that relay optical video information to a PC or Laptop (visualization/ annotation module).	The camera has optics that relays optical video information to the visualization/ annotation module.
Device Specifications: Light		
Light Module	Single loop group LED light	Single loop group LED light (C3A), Double loop group LED light (C6A)
Light Source	White and Green LED light	White LED light/ Green Filter
Max. Illumination	20,000 lux at working distance of 5mm 462 lux at working distance of 50mm	1600 lux at working distance 300 mm (C3A) 3000 lux at working distance 300 mm (C6A)
Illumination Range/ Beam Diameter	74.5 mm at working distance of 50 mm	≥ Φ 60 mm at working distance 200 mm
Light Source Lifetime	≥ 10,000 hrs	Same
Device Specifications: Camera		
Magnification	3 X ~ 52 X	1 ~ 28X (C3A) 1 ~ 36X (C6A)
System Resolution	≥ 1944 TVL	≥500 TVL
Optical Resolution	Lowest: 13.51 lp/mm Highest: 121.02 lp/mm	≥10 lp/mm

Table 1: Substantial Equivalence Table Comparison		
	Subject Device	**K151878**
Image Geometric Distortion	+0.3% to -3.24%	<3%
Working Distance	5 – 50 mm	200 – 300 mm
Field of View (FOV)	At min. magnification ≥ 54.2 mm At max. magnification ≥ 5.87 mm	At min. mag. ≥Φ80 mm At max. mag. ≥ Φ12 mm
Depth of Field	At min. magnification 11.71 mm At max. magnification ≥ 1.86 mm	At min. mag. ≥120 mm At max. mag. ≥6 mm
Focus Mode	Manual control: Auto focus only	Electronic control: Manual and auto focus
Video Output	USB	S-Video
Freeze Function	Yes	Yes
Vascular Visualization	Green LED light	Electronic Filter: Green filter (3 grades)
Cleaning	Handle and Cord: Surfaces disinfected with disinfectant wipe Probe: High Level Disinfection	Surfaces disinfected with disinfectant wipe
Radiation safety:	Does not emit any ionizing radiation	Does not emit any ionizing radiation

The subject and predicate device have different indications for use statements, as the subject device can be inserted into the vagina via a speculum. However, the subject and predicate device have the same intended use - magnified viewing of the vagina, cervix and external genitalia to assist doctors in diagnosing abnormalities and select areas for biopsy.

As evidenced by the table above, the subject and predicate device have different technological characteristics. These differences in technological characteristics do not raise different questions of safety or effectiveness.

Summary of Performance Testing:

The following performance tests were conducted in support of the substantial equivalence determination. All test results met pre-determined acceptance criteria.

- **Electrical Safety and Essential Performance Requirements –** The Pocket Colposcope System was tested to verify safety and essential performance requirements and complies with the following standard:
    - IEC 60601-1:2005, + A1:2012

- **Electromagnetic Compatibility (EMC) –** The (EMC) series of test demonstrates the EMC characteristics of the Pocket Colposcope System. The Pocket Colposcope was tested to the requirements of and complies with the following standards:

  - IEC 60601-1-2 (2014) Medical Device
    - IEC 61000-4-2 (2008) – Electrostatic Discharge
    - IEC 61000-4-3 (2006), A1(2007), A2(2010) – Radiated Immunity
    - IEC 61000-4-4 (2012) – Electrical Fast Transient/ Burst
    - IEC 61000-4-5 (2006) – Surge
    - IEC 61000-4-6 (2013) – Conducted Immunity
    - IEC 61000-4-8 (2009) – Magnetic Field Immunity
    - IEC 61000-4-11 (2004) – Voltage Dips & Variations
    - CISPR 11 Emissions Class A (2009), A1(2010)
    - CISPR 11 (EN 55011) – Radiated Emissions
    - CISPR 11 (EN 55011) – Conducted Emissions

- **Software Verification and Validation Testing –** The Pocket Colposcope firmware/software verification and validation testing were conducted and documented as recommended by FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software's level of concern for this device was considered as minor.

- **Imaging Evaluation –** The performance specifications associated with the features associated with imaging were tested to show the effectiveness of the subject device, including:
  - 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
  - ISO 9039:2008 - Optics and Photonics – Quality Evaluation of Optical Systems – Determination of Distortion
  - ANSI/ NEMA FL-1:2009 – Flashlight Basic Performance Standard for Illumination
  - IEC/EN 62471:2008 - Photobiological Safety of Lamps and Lamp Systems

- **Design Validation –** The design was validated through an evaluation of the Pocket Colposcope System by several trained medical professionals (intended users). The devices performed as intended and met the user's needs and requirements.

Conclusion:

The results of the testing demonstrate that the Pocket Colposcope System met all acceptance criteria and is as safe and effective as the predicate device and supports a determination of substantial equivalence.