November 27, 2018

Biop Medical Ltd.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street
Philadelphia, PA 19103

Re: K182764
Trade/Device Name: Biop Digital Colposcope
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: September 28, 2018
Received: September 28, 2018

Dear Janice M. Hogan:

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,

Sharon M. Andrews -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)*
K182764

Device Name
Biop Digital Colposcope

Indications for Use *(Describe)*
The Biop Digital Colposcope is intended for 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 the Digital Colposcope are to be viewed on a color display. The Biop Digital Colposcope is intended for use in hospitals, clinics, and doctor's offices.

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 – K182764

Biop Medical's Biop Digital Colposcope

1. Submitter's identification

Biop Medical Ltd.
10 O'haliav Street
Ramat-Gan, 5252263, Israel
Phone: +972-3-9444670
Contact Person: Ilan Landesman
Date Prepared: November 20, 2018

2. Name of Device

Name of Device: Biop Digital Colposcope
Common or Usual Name: Digital Colposcope
Classification: 21 CFR 884.1630
Classification Name: Colposcope
Regulatory Class: II
Product Code: HEX
Product Code Name: Colposcope (and colpomicroscope)

3. Predicate and Reference Device information

Predicate: K122973, MedGyn Products Inc., MedGyn AL-106 Digital Video Colposcope
Reference: K161871, Mobile ODT, The Eva (Enhanced Visual Assessment) System

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

4. Device Description

The Biop Digital Colposcope comprises 3 components:

- Biop Digital Colposcope Control unit;
- Biop Digital Colposcope unit;
- Dedicated PC (touch screen) containing software and vertical stand.

The Biop Digital Colposcope is designed to be utilized at a working distance (WD) of 8'' (200mm) - 12'' (300mm) from the cervix and acquires magnified images according to the doctor's requirements. The colposcope includes LED illumination and digital green filter capabilities as well.

The user can operate the Biop Digital Colposcope unit using the keypad on the Biop Digital Colposcope Control unit and/or via the touch screen of the PC. Via the operation screen on the monitor, the user can visualize the cervix, take snapshots, take video, and use the green filter and additional illumination functionalities. Each of these functions can be controlled and adjusted by designated menus.

The touch-screen graphical user interface (GUI) consists of three menu options: Menu 1, 2, or 3, which allow control over the Biop Digital Colposcope, including the illumination system, zoom functions and Pan options. Each Operation Screen can be used during the colposcopy exam and shows the video taken by the Biop Digital Colposcope camera in real time. Images acquired during colposcopy are shown on the right of the screen. The user can toggle through all images obtained via the Biop Digital Colposcope unit and, if indicated, can acquire the biopsies in a standard manner. In addition, the system also enables full screen presentation of the images.

5. Indications for Use

The Biop Digital Colposcope is intended for 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 the Digital Colposcope are to be viewed on a color display. The Biop Digital Colposcope is intended for use in hospitals, clinics, and doctor's offices.

The predicate MedGyn's AL-106 Digital Video Colposcope (K122973) is intended for 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 the predicate device are to be viewed on a color monitor. The predicate device is intended for use in hospitals, clinics, and doctor's offices.

The Biop Digital Colposcope and the predicate device have the same intended use - to permit direct viewing and imaging of the tissues of the vagina, cervix and external genitalia to assist doctors in diagnosing abnormalities and select areas for biopsy.

6. Summary of Technological Characteristics and Comparison

The Biop Digital Colposcope has similar technological characteristics as the predicate device, *i.e.*, both devices incorporate illumination, power and video into stand-alone units. They provide image capture function at the same working distance and resolution and record images of the examined area. They also have focusing, magnification and green filter capabilities. The technological characteristics of the subject and predicate devices are summarized in the table below.

Specification	Subject Device: Biop Digital Colposcope	Primary Predicate Device: AL-106	Discussion of Substantial Equivalence
Manufacturer / K#	Biop Medical / K182764	MedGyn / K122973	N/A
Intended Environment	Hospitals, clinics, and doctor's office	Hospitals, clinics, and doctor's office	Same
Standard configuration	CMOS digital camera, stand, PC and touch screen	Digital HAD CCD camera, Stand	Different; Biop digital colposcope has additional components: PC and touch screen. These additional components do not affect device output, which is similar to the predicate device. This difference does not raise different questions of safety and effectiveness.
Voltage	100 V – 240 V~	100 V – 240 V~	Same
Frequency	50 Hz / 60 Hz	50 Hz / 60 Hz	Same
Energy Used and/or delivered	White LED light	White LED light	Same
Illumination	2200 Lux at WD of 300 mm Diameter > 60 mm at WD of 200 mm	Not specified	Different; images provided are similar to the predicate device. The difference does not raise different questions of safety and effectiveness.
On – axis spatial resolution	57 line-pairs/mm	11.37 line-pairs/mm	Different; images are similar to the predicate device. The difference does not raise different questions of safety and effectiveness.
On – axis angular resolution	0.005°	0.02534°	Different; images are similar to the predicate device. The difference does not raise different questions of safety and effectiveness.
Geometric Distortion	<3%	≤3%	Same
Working Distance	200 mm – 300 mm	200 mm – 300 mm	Same

Specification	Subject Device: Biop Digital Colposcope	Primary Predicate Device: AL-106	Discussion of Substantial Equivalence
Field of View	At working distance of 8'' (200 mm): At minimum magnification 28° or ≥φ99 mm. At maximum magnification 3.4° or ≥φ11.8 mm At working distance of 12'' (300 mm): At minimum magnification 30° or ≥φ160 mm. At maximum magnification 3.8° or ≥φ20mm	At working distance of 200mm: At 1X magnification 52° or ≥φ195 mm. At 32X magnification 2° or ≥φ6.978 mm	Different; Biop digital colposcope has a larger FOV than the predicate at maximum magnification; however, its resolution is equivalent to the predicate. This difference does not raise different questions of safety and effectiveness.
Depth of Field	85mm (at 200mm) -95mm (at 300mm)	5mm-120mm	Different; Depth of field is within range of predicate. This difference does not raise different questions of safety or effectiveness.
Focus mode	Manual	Automatic / Manual	Different; User has manual control over focus like the predicate. Colposcopes with manual focus only have been previously cleared (K161871, EVA System). This difference does not raise different questions of safety or effectiveness.
Filter	Digital green filter, polarizing/glare reducing filter	3 grades of green filter	Different; The additional polarizing filter reduces glare in images and does not impair image quality or alter the imaging modality. The digital green filter performs the same function as the predicate's green filter. A digital green filter is used in the previously cleared EVA System. The differences in filters does not raise different questions of safety and effectiveness.
Magnification	Optical magnification: x3.7-x30 at 8'' (200mm) working distance	Optical magnification: x1-x36 Digital magnification: 1-40x	Different; minimum optical magnification is higher (x3.7) than the predicate (x1) and maximum magnification is slightly lower (x30) than the predicate (x36). However, clinical functionality is substantially equivalent. The difference does not raise different questions of safety and effectiveness.

Specification	Subject Device: Biop Digital Colposcope	Primary Predicate Device: AL-106	Discussion of Substantial Equivalence
Freeze function	Yes	Yes	Same
Video output	USB 3.0	S-Video	Different; Biop digital colposcope has a digital signal output, while predicate device has an analog signal output. This difference does not change device output and does not raise different questions of safety or effectivness.

7. Summary of Performance Data

Bench testing was performed per the following voluntary performance standards or FDA guidance:

Standards No. or Guidance	Standard or Guidance Title	Results
ISO 8600-1:2005	Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements	This testing demonstratedthat the Biop Digital Colposcope met its predefined optical specifications.
ISO 8600-3: 1997/Amd 1:2003	Optics and optical instruments - Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics	This testing demonstrated that the field of view and direction of view of the Biop Digital Colposcope met predefined specifications.
ISO 8600-5:2005	Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics	This testing demonstrated the optical resolution of the Biop Digital Colposcope met predefined specifications.
ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	The Biop Digital Colposcope was demonstrated to be basic safety compatible in its intended environment.
IEC 60601-1-2:2014 (Edition 4)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - requirements and tests	The Biop Digital Colposcope was demonstrated to be electromagnetically compatible in its intended environment.
IEC 62471	Photobiological safety of lamps and lamp systems	The Biop Digital Colposcope was demonstrated to be photo biologically safe in its intended environment and classification.

Standards No. or Guidance	Standard or Guidance Title	Results
ASTM D4169-16	Standard practice for performance testing of shipping containers and systems	The Biop Digital Colposcope, inside its package, successfully passed the environmental tests to ensure that it can withstand the expected distribution environment.
ASTM D4332-14	Standard practice for conditioning containers, packages, or packaging components for testing	The Biop Digital Colposcope, inside its package, successfully passed the environmental conditioning tests to ensure that it can withstand the expected distribution environment.
FDA guidance	"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005	The Biop Digital Colposcope software has been demonstrated to meet all Software Requirements Specifications. Software documentation reflected a Moderate Level of Concern.

8. Conclusions

The Biop Digital Colposcope is as safe and effective as the MedGyn AL-106 Digital Video Colposcope. Performance data demonstrate that the Biop Digital Colposcope is as safe and effective as the MedGyn AL-106 Digital Video Colposcope. Thus, the Biop Digital Colposcope is substantially equivalent to the predicate.