DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19, 2016

MobileODT Ltd.
Jen Acobas
RA/QA Manager
Ben Avigdor 8, 3rd Floor
Tel Aviv, 6721832
Israel

Re: K161871
Trade/Device Name: EVA (Enhanced Visual Assessment) System
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: Class II
Product Code: HEX
Dated: November 29, 2016
Received: November 29, 2016

Dear Jen Acobas,

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,

Benjamin R. Fisher -S

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)*
K161871

Device Name
EVA (Enhanced Visual Assessment) System

Indications for Use *(Describe)*
The EVA (Enhanced Visual Assessment) System is intended to provide magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The device is intended for use in hospitals, doctor's offices, and remote and rural clinics.

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

K161871

1. Submitter Information

Manufacturer Name and Address
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Phone: (617) 454-4687

Official Correspondent
Jennifer Acobas, VP Regulatory
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Phone: (617) 454-4687

2. Date Prepared: December 14, 2016

3. Device Information

Proprietary Name: EVA (Enhanced Visual Assessment) System

Common Name: Colposcope

FDA Classification Name: 21 CFR 884.1630; Colposcope

FDA Classification: Class II, Product Code: HEX

4. Predicate Device

The EVA System is substantially equivalent to the following device:

Manufacturer	Device	510(k)	Date Cleared
MedGyn Products, Inc.	MedGyn Digital Video Colposcope	K122973	June 12, 2013

5. Device Description

The EVA (Enhanced Visual Assessment) System is intended to provide magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and

selecting areas for biopsy. The EVA System is a handheld device in which a smartphone is fitted and consists of a colposcope body, lens, smartphone upper and lower brackets, LED electronics, CervDx app for image capture, and online portal for image transfer and remote viewing. The device also includes the strap, carrier case, and instruction manual. During colposcopy, the operator may mount the EVA System on a tripod for hands free imaging, turn on the LED light for improved viewing, see a magnified view of the vagina and cervix on a smartphone screen resting at the back of the device, annotate and save images on the CervDx app, and upload images to the portal. The EVA System is compatible with Motorola G2 and Motorola G3 smartphones.

The EVA System is capable of working for ten hours before recharging. The EVA System weighs about 0.5 kg and is light enough that the device can be operated for 10 minutes at a time without any fatiguing.

The device operates at a working distance of 22.5 - 42.5 cm with an optical magnification up to 4.0x and ultimately up to 16x, with digital zoom.

6. Indications for Use

The EVA (Enhanced Visual Assessment) System is intended to provide magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The device is intended for use in hospitals, doctor's offices, and remote and rural clinics.

7. Predicate Comparison

The following table compares the EVA System to the predicate device with respect to indications for use, technological characteristics, and materials:

Device & Predicate Device(s):	Subject Device: EVA System K161871	Predicate Device: MedGyn Digital Video Colposcope K122973
Indications for Use	The EVA (Enhanced Visual Assessment) System is intended to provide magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities	Medgyn's digital video colposcope is intended for magnified viewing of the tissues of the vagina, cervix and external genitalia in order to assist doctors in diagnosing

	and selecting areas for biopsy. The device is intended for use in hospitals, doctor's offices, and remote and rural clinics.	abnormalities such as lesions or cancer, and selecting areas for biopsy. The images from the digital video colposcope are to be viewed on a color monitor. The digital video colposcope is intended for use in hospitals, clinics, and doctor's offices.
Device Characteristics		
Working Distance	225-425mm	200-300mm
Focusing Mechanism	Manual	Autofocus, manual
Magnification	225:16x 425: 15x	1-40x
Digital Magnification	1x-4x	1-32x (model 106A: 1-40x)
Optical magnification	225: 4.0x 425: 3.8x	1-18x (model 106A: 1-36x)
Depth of Field	17mm (at 225mm) – 34mm (at 425mm)	5-120mm
Field of View	45mm (at 225mm) – 100mm (at 425mm)	1x: ≥60mm 32x: ≥6mm At working distance 200mm 1x: 195mm (52°) 32x: 6.98mm (2°)
On-axis Spatial Resolution	11.78 line-pairs/mm	11.31 line-pairs/mm
On-axis Angular Resolution	0.022°	0.02534°
Distortion	≤ 2.5%	2.49%
Light Source	3W 6500k star LED	Double circular LED group
Color	Digital green filter, polarizing/glare reducing filter	3 Grade filter function
Image Output	Image capture, cloud patient recording and image exporting	S-Video
Image Freeze	Full image capturing support	Image Freeze Control
Illuminance	≥1000lux at working distance 425mm	When working distance is 300mm, ≥ 1600 1x When working distance is 200mm,

		≥ 2000 1x
Controls	Interactive GUI mobile application Timers – Acetic Acid Timer	"Multi-function" button control Timers- Magnification & Acetic Acid Timer
Materials	PU – Biresin RG53 FR 6061 Aluminum 5052 Aluminum Stainless Steel	Not Available

The EVA 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.

8. Non-Clinical Performance Testing

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

- AAMI/ANSI 60601-1 (2012), Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod).
- IEC 60601-1-2 (Edition 3.0, 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.
- The EVA System was further tested for the following:
    - Power Consumption
    - Battery Lifetime
    - Image Distortion
    - Cervical Model Image Quality
    - Image Pairs Evaluation
    - Working Distance

- Illuminance

- Validation of the device software was performed according to the clause 14 of IEC 60601-1 (third edition) Software requirements, IEC 62304:2004 to IEC 62304–2006/AC 2008, Medical device, and Software life-cycle processes standards.
- Usability testing was conducted according to the IEC 62366-1:2015 standard and FDA guidelines for Applying Human Factors and Usability Engineering to Medical Devices.

9. Clinical Performance Data

Not Applicable

10. Conclusion

Based on the comparison and analysis above, the EVA System is substantially equivalent to the predicate device.