May 8, 2019

Illumigyn Ltd.
℅ Ahava Stein
Regulatory Consultant
A. Stein Regulatory Affairs Consulting Ltd.
20 Hataas St., Suite 102
Kfar Saba, 4442520
Israel

Re: K190187
Trade/Device Name: Gynescope™ System
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX, HIB
Dated: January 29, 2019
Received: February 7, 2019

Dear Ahava Stein:

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
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K190187

Device Name
Gynescope™ System

Indications for Use *(Describe)*
The Gynescope™ System is intended for the examination of the tissues of the vagina, cervix, and external genitalia, to investigate, by means of magnification, abnormalities such as lesions or cancer. The Gynescope™ System is intended to select areas for biopsy, when indicated.

The Gynescope™ Single Use Vaginal Speculum component of the Gynescope™ System is used to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures. The Gynescope™ Single Use Vaginal Speculum can be used only with the Gynescope™ System.

The Gynescope™ System is intended for use in hospitals, clinics, and doctors' 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.**

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

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**510(k) Summary**
**K190187**
**Gynescope™ System**

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**Date Prepared:** April 29, 2019

**Trade Name:** Gynescope™ System

**Common Name:** Colposcope

**Regulation Number:** 21 CFR 884.1630

**Regulation Name:** Colposcope

**Product Code:** HEX (Colposcope [and Colpomicroscope]), HIB (Speculum, Vaginal, Nonmetal)

**Regulatory Class:** Class II

**Predicate Device:** MedGyn Digital Video Colposcope
MedGyn Products, Inc.
510(k) Number – K122973

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

**Device Description:**

The Gynescope™ System is a colposcope platform for physicians to perform examinations of the vagina, cervix and external genitalia. The Gynescope™ System consists of the following components:

- Gynescope™ Image Acquisition System (IAS)

- Gynescope™ System Console
- Gynescope™ Single Use Vaginal Speculum

The IAS is a handheld colposcope that includes imaging optics and provides white and green illumination using both centered and side illumination techniques. The IAS also includes color and monochrome sensors. The color sensor is used for standard examinations under white or green illumination, while the monochrome sensor is only used for imaging target tissues under green illumination. Key functions of the device (e.g., magnification, illumination, light source, image capture, etc.) can be operated using a built-in keypad on the IAS. A cable connects the IAS to the Gynescope™ System Console.

During use, the IAS is attached to the Gynescope™ Single Use Vaginal Speculum to form a single body. When combined, the Gynescope™ Single Use Vaginal Speculum provides access to the vaginal cavity and prevents direct contact of the IAS with the patient. This component also includes a separate opening for instruments if needed during an examination. The Gynescope™ Single Use Vaginal Speculum is non-sterile, made of polycarbonate, and is provided in four sizes.

The Gynescope™ System Console is responsible for data processing, storage and display of information to the user. In addition, the Gynescope™ System Console can be used to control functions of the IAS (e.g., magnification, illumination, light source, image capture, etc.). User's interact with the Gynescope™ System Console via a 12.2-inch touchscreen interface. This component also includes a video output connection that allows connection to a peripheral video device (e.g., monitor). A cradle is also mounted on the Gynescope™ System Console that is used to hold and protect the IAS between uses.

**Indications for Use:**

The Gynescope™ System is intended for the examination of the tissues of the vagina, cervix, and external genitalia, to investigate, by means of magnification, abnormalities such as lesions or cancer. The Gynescope™ System is intended to select areas for biopsy, when indicated.

The Gynescope™ Single Use Vaginal Speculum component of the Gynescope™ System is used to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures. The Gynescope™ Single Use Vaginal Speculum can be used only with the Gynescope™ System.

The Gynescope™ System is intended for use in hospitals, clinics and doctors' offices.

**Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices**

| **Technological Characteristic** | **Gynescope™ System Illumigyn Ltd. K190187 Subject Device** | **MedGyn Digital Video Colposcope MedGyn Products Inc. K122973 Predicate Device*** | **Comments** |
|---|---|---|---|
| **Indications for Use** | The Gynescope™ System is intended for the examination of the | Medgyn's digital video colposcope is intended for magnified viewing of | **Different -** Although the indications statements are not identical, the subject |

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| | tissues of the vagina, cervix, and external genitalia, to investigate, by means of magnification, abnormalities such as lesions or cancer. The Gynescope™ System is intended to select areas for biopsy, when indicated.<br><br>The Gynescope™ Single Use Vaginal Speculum component of the Gynescope™ System is used to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures. The Gynescope™ Single Use Vaginal Speculum can be used only with the Gynescope™ System.<br><br>The Gynescope™ System is intended for use in hospitals, clinics and doctors' offices. | 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 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. | and predicate devices have the same intended use – viewing the vagina, cervix, and external genitalia to aid in diagnosing abnormalities such as lesions or cancer and selecting areas for biopsy. |
| Components | The Gynescope™ System consists of the following components:<br><br>• Colposcope (IAS)<br>• Single use vaginal speculum<br>• System console with touch screen | The MedGyn Digital Video Colposcope consists of the following components:<br><br>• Colposcope<br>• Stand | **Different –** The subject and predicate device both include colposcope components and the ability to display images on an external display. The subject device also includes a system console for data collection, image processing/display and storage, and a speculum that is required for subject device use. The predicate |

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| | | | device includes a stand for the colposcope, which is not a component of the subject device. These differences do not raise different questions of safety and effectiveness (S&E). |
| Working distance | 50-160 mm | 200-300 mm | **Different –** The subject device has a shorter working distance than the predicate device. This difference does not raise different questions of S&E. |
| Focusing mechanism | Auto-focus | Auto-focus, manual | **Different –** The subject device cannot be manually focused. This difference does not raise different questions of S&E. |
| Magnification | 3x-112x | 1-40x | **Different –** The overall subject device magnification is greater than the predicate device. This difference does not raise different questions of S&E. |
| Depth of field | 0.8-2 mm | 5-120 mm | **Different –** The subject device depth of field is lower than the predicate device. This difference does not raise different questions of S&E (e.g., optical resolution, etc.). |
| Field of View | 29mm - 70mm | At working distance 200 mm):<br>• 1x: 195 mm (52°)<br>• 32x: 6.98 mm (2°) | **Different –** The subject device field of view is different than the predicate device. This difference does not raise different questions of S&E (e.g., optical resolution, etc.). |
| On-axis Spatial Resolution | 16 line pairs/mm | 11.37 line pairs/mm | **Different –** The subject device resolution has more line pairs/mm than the predicate device. This difference does not raise different questions of S&E. |
| On-axis Angular Resolution | 0.016° | 0.02354° | **Different:** The subject device has a smaller on-axis angular resolution that the |

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| | | | predicate device. This difference does not raise different questions of S&E. |
| Distortion | ≤2% | ≤2.49% | **Similar** |
| Light source | White and green LED light sources | White LED light source | **Different –** The subject device includes a green light source in place of a green filter. This difference does not raise different questions of S&E (e.g., light safety, etc.). |
| Illumination | ~20000 lux at a 50 mm working distance<br><br>~1000 lux at a 160 mm working distance | Not specified | **Different –** Predicate device illumination information is not known; however, any differences would not raise different questions of S&E (e.g., light safety, software control of light intensity, etc.). In addition, the illumination intensity for the subject device is within the range of other cleared devices of this type. |
| Green filter | No | Yes | **Different –** The subject device uses green illumination instead of a green filter. This difference does not raise different questions of S&E (e.g., light safety, etc.). |
| Image Output | Output to view screen on the Gynescope™ System Console and to an external monitor via a DVI-D video output. | S-Video output to monitor | **Different –** The subject device includes a console component that is used to process, display and store data collected from the IAS. Images from the subject can also be displayed on a separate external monitor. The predicate sends image information to a connected monitor for viewing. This difference does not raise different questions of S&E. |
| Image Freeze Function | Yes | Yes | **Same** |
| Speculum | Single-use speculum designed to connect to | Not a component of the predicate device | **Different –** The subject device requires the use of a |

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| | the IAS required for device use | | specialized speculum, while the predicate is used with a marketed speculum, which is not provided. This difference does not raise different questions of S&E. |
| Sterility | Device components are non-sterile. | The device is not intended to be sterile | **Same** |

As shown above, the indications for use of the subject Gynescope™ System is not identical to the predicate device; however, the differences do not represent a new intended use as both devices are used for viewing the vagina, cervix, and external genitalia to aid in diagnosing abnormalities such as lesions or cancer and selecting areas for biopsy.

Regarding technological characteristics, the subject and predicate devices have some similarities in their designs. However, many differences exist as described in the table above (e.g., optical parameters, components, etc.). The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device as stated in the table.

**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 –** The Gynescope™ System was tested and shown to comply with the following electrical safety standards:

- IEC 60601-1:2005, + A1:2012
- IEC 60601-1-11 Edition 2.0 2015-01
- IEC 60601-2-57 Edition 1.0 2011-01

**Electromagnetic Compatibility (EMC) –** The Gynescope™ System was tested and shown to comply with the IEC 60601-1-2:2014.

**Software Testing –** Software for the Gynescope™ System was provided in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software level of concern for this device was considered as minor.

**Cybersecurity –** Cybersecurity information for the Gynescope™ System was provided in accordance with FDA's guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

**Imaging Evaluation –** The performance of the imaging features of the Gynescope™ System was assessed as follows:

- Field and depth of view per ISO 8600-3:1997
- Optical resolution per ISO 8600-5:2005
- Image distortion
- Color performance testing

- Illumination intensity at different working distances
- Photobiological safety per IEC 62471: 2006

**Gynescope™ Single Use Vaginal Speculum Testing:**

- Biocompatibility testing – the following tests were conducted on the patient-contacting materials of the speculum:

    - Cytotoxicity per ISO 10993-5:2009
    - Vaginal irritation per ISO 10993-10:2010
    - Guinea pig maximization sensitization testing per ISO 10993-10:2010

  Testing showed the Gynescope™ Single Use Vaginal Speculum materials to be non-cytotoxic, non-irritating, and non-sensitizing.

- Mechanical testing on the speculum to assess breakage forces. All devices passed the pre-defined acceptance criterion.

- Compatibility of the speculum with gynecologic tools and instruments. Testing showed that common instruments used during colposcopy examinations (e.g., biopsy punch and PAP smear collection device) were compatible with the working channel of the Gynescope™ Single Use Vaginal Speculum.

**Conclusion**
The results of the performance testing described above demonstrates that the subject devices are as safe and effective as the predicate devices and supports a determination of substantial equivalence.