GYNIUS AB
510(k) submission Gynocular Colposcope

APR 0 8 2014

5. 510(k) Summary

April 4th, 2014

(1) Submitter Information

Name: Gynius AB
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Contact Person: Matthew Volsky CEO - Gynius AB

(2) Name of Device

Trade Name: Gynocular
Common Name: Colposcope
Classification: Colposcope, 21 CFR 884.1630, Class II
Product Code: HEX

(3) Predicate devices

Applicant	Medgyn Products, Inc.	Intermed Group Inc.	Medgyn Products, Inc.	Wallach Surgical Devices, Inc.
Device Name	Digital Colposcope & Image Management System	The Intermed Zoom Colposcope	Gynescope	Wallach Zoom Colopscope
Model	AL-106	IZM-310	AL 103	ColpoStar IH
K-Number	K122973	K031629	K880195	K853389

(4) Device Description

The Gynocular is a hand-held, colposcope, which provides a magnified visualization of the tissues of the cervix, vagina, vulva and anogential area. It is used to evaluate these tissues and select areas for biopsy, without contacting the patient. The user is a medical physician, or a trained colposcopist.

The Gynocular is a colposcope with similar specifications to traditional colposcopes. The Gynocular has a 300 mm focal distance, 3-magnifications: 5x, 8x, and 12x. It is a handheld device that comes with a tripod-mounting clip that screws into a standard tripod enabling the

medical professional to also perform colposcopy hands-free mode for ease of biopsy. The Gynocular uses high intensity LEDs for illumination, has a green filter, and is powered by a rechargeable lithium-ion battery. We also provide a charging base for the Gynocular.

(5) Indications for use (colposcopy):

The Gynocular is intended to provide magnified visualization of the tissues of the vagina, cervix and external genitalia. It is used to evaluate these tissues and select areas for biopsy.

(6) Comparison to Predicate Devices

Applicant	**Medgyn Products, Inc.**	**Intermed Group Inc.**	**Medgyn Products, Inc.**	**Wallach Surgical Devices, Inc.**	**Gynius AB**
Device Name	Digital Colposcope & Image Management	The Intermed Zoom Colposcope	Gynescope	WALLACH ZOOM COLPOSCOPE	The Gynocular
Model	AL-106	IZM-310	AL 103	ColpoStar IH	V1
K-Number	K122973	K031629	K880195	K853389	n/a
Magnification	Optical 36x Display ;	Standard 10x	4.3x/7x/11.3x	12x	5x/8x/12x
Working distance	200-300 mm	310 mm	300 mm	300 mm	300 mm
Lamp	LEDs	Halogen	Halogen	Halogen	LEDs
Filter	Green filter	Green filter	Green filter	Green filter	Green filter
Ocular type	Monocular	Binocular	Binocular	Binocular	Monocular
Stand	Stationary	Stationary	Stationary	Stationary	Portable/stationary on a tripod.
Energy source	Standard AC Power Supply	Standard AC Power Supply	Standard AC Power Supply	Standard AC Power Supply	Lithium-ion Battery

The Gynocular's performance specifications are substantially equivalent to the listed predicate devices.

(7) Performance Data

The following testing was conducted to support a substantial equivalence determination.

- Distortion testing:
  The analysis shows that the Gynocular exhibits a minimal Barrel type geometrical distortion: 0.47%, 0.75% and 0.81% for 5x, 8x and 12x magnification, respectively. This distortion is at levels of professional camera lenses considered and is considered negligible for a visual examination of tissue. The analysis shows that the Gynocular exhibits a

negligible chromatic distortion: 3.3 µm, 5.8 µm and 3.3 µm for 5x, 8x and 12x magnification, respectively. This chromatic distortion is equal and below the levels of visual acuity of the human eye (5-6 µm at the retina).

- Magnification testing:
  4.81x ±0.15, 7.74x ±0.15, 12.40x ±0.15

- Optical resolution:
  5x = 28.6 cy/mm
  8x = 40.5 cy/mm
  12x = 56.8cy/mm

- Design validation:
  Firmware and mechanical tests were conducted to demonstrate that the mechanical functions and optical properties achieve the desired results.

- Thermal safety:
  After 1hr 55 min of continuous use, the Gynocular's outer heat sink reached 39.1 degrees C in an ambient temperature setting of 24 degrees C. The Gynocular has an automatic shut off mechanism if temperatures become unsafe.

- Battery Performance:
  The typical charging time from empty to full charge is 2.5 hours or less. The battery gives approximately 2hrs of illuminator on time (full intensity) from a full charge. The use of life for the battery is 500 full charging cycles.

Non-clinical tests

Appropriate risk analysis-driven product testing was conducted to evaluate product safety. The following standards were met:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
- EN 60601-1 2006

Clinical tests

Gynius conducted a randomized, crossover, pilot clinical trial for evaluating agreement of diagnosis of cervical lesions by colposcopy using a standard colposcope and the Gynocular. The study population was 69 women that tested positive for visual inspection with acetic acid. Swede scores were given at the time of colposcopy and compared with the final histological diagnosis after directed cervical biopsy. The Swede scores were compared across the two techniques and there was a 70% agreement overall. Conclusions: The study shows that in visual inspection with acetic acid positive women, a battery-driven, pocket-sized colposcope – the Gynocular, has a significant level of agreement with a stationary colposcope in assessing cervical lesions. The study was accepted and published by The Journal of Lower Genital Tract Disease in May 2013.

(8) Conclusions

The Gynocular is equivalent in safety and efficacy to the legally marketed predicate devices.

510(k) Submission
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2014

Gynius AB
Matthew Volsky
CEO
Dobelnsgatan 23
Stockholm 11140
Sweden

Re: K132423
Trade/Device Name: The Gynocular
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: March 6, 2014
Received: March 10, 2014

Dear Matthew Volsky,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

GYNIUS AB

510(k) submission
Gynocular™ Colposcope

4. Indications for Use

510(k) Number: **K132423**

Device Name: The Gynocular

Indications for Use:

The Gynocular is intended to provide magnified visualization of the tissues of the vagina, cervix and external genitalia. It is used to evaluate these tissues and select areas for biopsy.

Prescription for Use: X

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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