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

October 23, 2014

Cooper Surgical, Inc.
% Tim Lohnes
Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, CT 06484

Re: K140754
Trade/Device Name: Cooper Surgical Leisegang Colposcope System
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: September 19, 2014
Received: September 23, 2014

Dear Tim Lohnes,

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

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)*
K140754

Device Name
Leisegang Colposcope Systems

Indications for Use *(Describe)*
The Cooper Surgical Leisegang Colposcope Systems are intended for the 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 Cooper Surgical Leisegang Colposcopes may be viewed directly and/or on a color monitor (if so equipped). Cooper Surgical Leisegang Colposcopes are 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Trumbull, Connecticut
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510(K) SUMMARY:

SUBMITTER:	Cooper Surgical, Inc. 75 Corporate Drive, Trumbull, CT 06611
CONTACT PERSON:	Tim M. Lohnes, Senior Regulatory Consultant, Orchid Design, 80 Shelton Technology Center Shelton, CT 06484 203-922-0105
DATE PREPARED:	October 22, 2014
TRADE/PROPRIETARY NAME:	Cooper Surgical Leisegang Colposcope Systems System(s)
COMMON/USUAL NAME:	Colposcope (colpomicroscope) and Accessories
CLASSIFICATION NAME:	Class II: Obstetrical and Gynecological Diagnostic Devices CFR Section: 21 CFR 884.1630
PREDICATE DEVICE(S):	Leisegang Colposcope(s), K940094, Galileo Corp. Leisegang Video Colposcope, K981958, MedGyn Products, Inc. Digital Video Colposcope, K122973.

DEVICE DESCRIPTION:

The Cooper Surgical Leisegang Colposcope(s) and accessories are optical colposcopes designed for non-contact visualization of the tissues of the cervix, vulva, vagina, and anogenital areas. Depending on the model and/or mode selected, they provide direct visual, photographic, and/or high resolution color imaging of the selected area.

INTENDED USE:

Non-contact visualization of the tissues of the cervix, vulva, vagina, and anogenital areas.

INDICATIONS FOR USE:

The Cooper Surgical Leisegang Colposcope Systems are intended for the 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 Cooper Surgical Leisegang Colposcope Systems may be viewed directly and/or on a color monitor (if so equipped). The Cooper Surgical Leisegang Colposcope Systems are intended for use in hospitals, clinics, and doctor's offices.

TECHNOLOGICAL CHARACTERISTICS:

The Cooper Surgical Leisegang Colposcope(s) are 300mm working distance binocular colopscope(s), consisting of an objective lens, binocular tubes, adjustable oculars (eyepieces) to provide compensation for myopia and hyperopia, a magnification changer and green filters (as applicable), and LED illumination, incorporated in a common housing.

All Cooper Surgical Leisegang Colposcope(s) models are based on 3 versions of the scope body;

1) non-photographic, which provide visual imaging (via the oculars) only,

2) external photographic, to which a standard digital camera can be mounted to the scope body via a standard bayonet mount; the camera image corresponds to the image provided via the oculars.

3) integral photographic, with a ¼" IR CCD color camera integral to the scope body; the camera image corresponds to the image provided via the oculars. There are two integral cameras available, one providing analog S-Video (NTSC) output, and a digital unit which provides video output via a UBS cable.

SCOPE OPTIONS:

The basic Cooper Surgical Leisegang Colposcope(s) described above can be provided with various options, including;

1) Fixed magnification of 15x (non-photographic models only), and variable magnification ranges of 3.75, 7.5, 15x, or 7.5, 15.0, 30.0x.

2) 0° (straight) or 45° oculars.

3) Green filters (not available with the 45° oculars).

ACCESSORY OPTIONS:

There are various accessories available for the Cooper Surgical Leisegang Colposcope(s), including stands, cameras, monitors (where applicable), The Cooper Surgical Order Code denotes the Scope, Scope options, and the accessories included in that particular Order Code. The Order Codes are listed in detail in this Summary.

MATERIALS:

The Cooper Surgical Leisegang Colposcope(s) and accessories are not indicated or intended for patient contact; therefore the materials used in their construction have not been specifically evaluated for biocompatibility.

COMMON FEATURES and SPECIFICATIONS;

The following features and specification are common to all models of Cooper Surgical Leisegang Colposcope(s) , regardless of any other features or options;

1) Illumination – Light Emitting Diode (LED)

2) Working Distance – 300mm for all models.

3) Diopter adjustment - ±7 for all models.

4) Interpupillary distance – individually, continuously adjustable on all models.

5) View Direction – with 0° oculars, straight, with 45° oculars, inclined.

6) Depth of Field – at the fixed Working Distance of 300mm ± 10mm, the Depth of Field at the specified 300mm working distance is 290mm to 310mm for all models.

7. Distortion – less than +7% at the specified 300mm Working Distance.

PERFORMANCE DATA:

Non-clinical testing and attribute comparisons have been used to establish that the features and performance of the subject devices are substantially equivalent to the predicates. The following attributes are listed below along with the specific Order Code

1) Resolution (referenced USAG Chart NBS 1963A)

2) Depth of Field, measured at the fixed Working Distance of 300mm

3) Distortion ≤ +7% at all magnifications

4) LED illumination testing - no significant spectrum below 400 nm, emission spectrum measured Ra=92, with no undesirable temperature rise in the subject field; the measured UV irradiance = 5.81569μW/m^2. Enclosure surfaces did not exceed 74°C.

NON-CLINICAL TESTING:

The following Performance Standards were met;

IEC 60601-1:2005 + COOR. 1 (2006) + COOR. 2 (2007), “Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential performance”,

IEC 60601-1-2: 2007 (3rd Edition), “Medical Electrical Equipment for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility”.

IEC 60601-2-41, "Medical Electrical Equipment Part 2-41: Particular requirements for the basic safety and performance of surgical luminaries and luminaries for diagnosis".

COMPARISION TO PREDICATE DEVICE(S):

The subject Cooper Surgical Leisegang Colposcope(s) and the Predicate devices have the same intended use, which is non-contact visualization of the tissues of the cervix, vulva, vagina, and anogenital areas.

Various design and manufacturing changes made to the Cooper Surgical Leisegang Colposcope(s) subsequent to the predicate clearances K940094 and K981958 were evaluated in detail and analysis provided which demonstrate that the Cooper Surgical Leisegang Colposcope(s) were substantially equivalent to the predicate(s).

The Cooper Surgical Leisegang Colposcopes with fixed 15x magnification yielded performance equivalent to the variable magnification devices when set to 15x.

The Cooper Surgical Leisegang Colposcope(s) demonstrate only slight differences in design, construction and specifications when compared to the predicates as well as the MedGyn device. The Cooper Surgical Leisegang Colposcope can be provided with integral video cameras and LED light sources, green filters, and various magnification levels.

CONCLUSION:

The Indications For Use for the Cooper Surgical Leisegang Colposcope(s) System is the same as the predicate devices, and the differences in features between the devices do not raise any new questions of safety or effectiveness. The evaluations conducted confirm the validity of the comparisons of the various attribute comparisons, establishing that the Cooper Surgical Leisegang Colposcope(s)System is substantially equivalent to the predicate device(s) .

ORDER CODES:

The Cooper Surgical Leisegang Colposcope(s) System Order Codes are listed below, including the various options and accessories associated with the specific Code.

Non-Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik1-00	*3.75, 7.5, 15x*	*0°*	*None*	*n/a*	*76, 38, 19mm*	*18, 18, 18*	*Tilt Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik1-01	*3.75, 7.5, 15x*	*0°*	*None*	*n/a*	*76, 38, 19mm*	*18, 18, 18*	*Rolling Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik1-02	*3.75, 7.5, 15x*	*0°*	*None*	*n/a*	*76, 38, 19mm*	*18, 18, 18*	*Swing Arm Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik1-03	*3.75, 7.5, 15x*	*0°*	*None*	*n/a*	*76, 38, 19mm*	*18, 18, 18*	*Balance-O-Matic Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
n/a	*7.5, 15, 30x*	*0°*	*None*	*n/a*	*46, 23, 11.5mm*	*18, 18, 18*	*na*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
TBD	*7.5, 15, 30x*	*45° (no green filter)*	*None*	*n/a*	*46, 23, 11.5mm*	*18, 18, 18*	*na*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
n/a	*15x Fixed*	*0°*	*None*	*n/a*	*23mm*	*18*	*n/a*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
n/a	*15x Fixed*	*0°*	*None*	*n/a*	*23mm*	*18*	*Tilt only*

Scope Head 3ML, External Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-05-002	*3.75, 7.5, 15x*	*0°*	*For 1.0" CCD*	*DSLR*	*76, 38, 19mm*	*18 Camera 5.6, 12.5, 18*	*Balance-O-Matic Stand*
US Model	**Mag**	**Ocular**	**Camera feature**	**Output**	**Field of View**	**Resolution**	**Note**
Optik2-04-002	*3.75, 7.5, 15x*	*0°*	*For 1.0" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Arm Stand & Camera*

Scope Head 3ML, External Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-03-002	*3.75, 7.5, 15x*	*0°*	*For 1.0" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Upright base*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-04	*3.75, 7.5, 15x*	*0°*	*For 1.0" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Arm Stand (no camera)*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-05	*3.75, 7.5, 15x*	*0°*	*For 1.0" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Balance-O-Matic (no camera)*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-04-004	*3.75, 7.5, 15x*	*0°*	*For 1.0" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Arm Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-04-007	*7.5, 15, 30x*	*45°*	*For 1.0" CCD*	*DSLR*	*46, 23, 11.5mm*	*18, Camera 7.1, 14, 18*	*No Green Filter*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-07-004	*3.75, 7.5, 15x*	*0°*	*For 1.0" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Tilt Base*

Scope Head 3ML, External Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-04-444	*7.5, 15, 30x*	*0°*	*For 1.0" CCD*	*DSLR*	*46, 23, 11.5mm*	*18, Camera 7.1, 14, 18*	*Swing Arm Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-13-003	*3.75, 7.5, 15x*	*0°*	*For .05" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Arm Base*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-14-008	*3.75, 7.5, 15x*	*0°*	*For .05" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Tilt Base*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-15-008	*3.75, 7.5, 15x*	*0°*	*For .05" CCD*	*DSLR*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Upright Base*

Scope Head 3MV, Integrated Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-06-007	*3.75, 7.5, 15x*	*0°*	*Integrated*	*1.3MP USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Base*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optok2-07-007	*3.75, 7.5, 15x*	*0°*	*Integrated*	*1.3MP USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Balance-O-Matic*

Scope Head 3MV, Integrated Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-13-003	*3.75, 7.5, 15x*	*0°*	*Integrated*	*1.3MP USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Arm Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-14-003	*3.75, 7.5, 15x*	*0°*	*Integrated*	*1.3MP USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Tilt Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-15-003	*3.75, 7.5, 15x*	*0°*	*Integrated*	*USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Rolling Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-10	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Tilt Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-10-001	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Tilt Stand & LCD monitor*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-11	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Upright Base*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-11-001	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Upright Base & LCD monitor*

Scope Head 3MV, Integrated Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-12	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Swing Arm Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-12-001	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Swing Arm Stand & LCD monitor*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-10-001	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Tilt Stand & LCD Monitor*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-11-001	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Rolling Stand & LCD Monitor*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-12-001	*3.75, 7.5, 15x*	*0°*	*Integral*	*S-Video, NTSC*	*76, 38, 19mm*	*18, Camera 4, 9, 16*	*Swing Arm Stand & LCD Monitor*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-14-003	*3.75, 7.5, 15x*	*0°*	*Integral*	*USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Tilt Stand*

Scope Head 3MV, Integrated Photographic Models

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-15-008	*3.75, 7.5, 15x*	*0°*	*Integral*	*USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Upright base*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-13-003	*3.75, 7.5, 15x*	*0°*	*Integral*	*USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Arm Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-13	*3.75, 7.5, 15x*	*0°*	*Integral*	*USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Swing Arm Stand*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-14	*3.75, 7.5, 15x*	*0°*	*Integral*	*USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*n/a*

US Model	Mag	Ocular	Camera feature	Output	Field of View	Resolution	Note
Optik2-15	*3.75, 7.5, 15x*	*0°*	*Integral*	*USB Digital*	*76, 38, 19mm*	*18, Camera 5.6, 12.5, 18*	*Rolling Base*