K101141
pg. 1 of 2

SEILER
INSTRUMENT
& MANUFACTURING COMPANY, INC.
3433 Tree Court Industrial Blvd.
St. Louis, MO 63122 USA
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Fax: 314-968-2637 Corporate
Fax: 314-968-9217 Survey
Fax: 314-968-3601 Microscope

Since 1945

Date: July 2010

AUG - 6 2010

Section 6.

510(k) Summary

We believe our product is (SE) Substantially Equivalent to a number of other devices currently approved by the FDA. Our device by common name is "COLPOSCOPE" a **Class II device, Product Code HEX.**

Common Name: Colposcope
Proprietary Name: Seiler Colposcope
Current models - Model 935 Series, Model 955 Series, Model 985 Series

Intended Use: A Colposcope is a device designed to permit viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose and examine abnormalities of the vagina and cervix and select areas for biopsy. This generic type of device may include a light source, cables, and components parts.

Indications for Use:

The Seiler colposcope is intended to provide magnified visualization of the tissues of the vulva, vagina, cervix, and anogenital area. It is used to evaluate these tissues, select areas for biopsy, as necessary, and to facilitate related procedures, e.g., LEEP, conization, etc.

Summary:

The Model 935 colposcope with a 300mm objective lens has 3-magnifications, 3x, 7x, and 17x. The optics are mounted on a column and roll-around base for easy access to the areas of examination.

The Model 955 colposcope with a 300mm objective lens has 5-magnification, 3x, 4x, 7x, 11x, and 17x. The optics are mounted on swing-arms on a roll-around base. This mounting system allows the user to "swing" the optics out of the way when not in use while storing the colposcope in a more permanent location close to the examination table.

The Model 985 colposcope with a 300mm lens also has 5-magnifications, 3x, 4x, 7x, 11x, and 17x. Like the Model 955, the optics are mounted on a swing-arm on a roll-around base, however the optics and arm can be swung into place from a stored position above and to the side of the user. This also allows the optics to be stored in a permanent location. An additional benefit of this mounting system is there are no mounting arms or a column directly in front of the user, allowing the user to utilize examining/surgical instruments in a clear work space directly in front of the areas of examination.

Most predicate colposcopes have an optical pod with various magnifications, a power supply, usually halogen, and a delivery system i.e. floor stand and base. We offer similar features, however our power unit has 2 modes of illumination which allows for the spare illumination to be accessed with a flip of a switch. This quick change feature means that if one of the illuminator lamps fails during an examination or procedure, the examination or procedure will not have to pause while a new lamp is installed.

ALL ELECTRICAL TESTING INCLUDING ELECTRICAL SAFETY, EMC TESTING, THERMAL TESTING, OPTICAL QUALITY TESTING AND TUV CERTIFICATION WERE PERFORMED BY CERTIFIED TESTING LABORATORIES. THE PRODUCT PASSED ALL TESTS. COPIES OF THE TEST RESULTS ARE LOCATED IN SECTIONS D. AND E. IN OUR SUBMISSION.

There are a number of predicate device colposcopes registered with the FDA. Please see below.

Classification Number: 21 CFR 884.1630
Regulation Name: Colposcope
Class II
Product Code: HEX

Company Name	**510(k) Number**
D.F. Vasconcellos	K021854
Jedmed Inst. Co	K884934
Leisegang	K940094

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Daniel Meyer
Microscope Consultant
Seiler Precision Microscopes
Seiler Instrument & Mfg Co., Inc.
3433 Tree Court Industrial Blvd.
ST. LOUIS MO 63122

AUG - 6 2010

Re: K101141
Trade Name: Seiler Colposcopes – Models 935, 955, & 985
Regulation Number: 21 CFR §884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: June 24, 2010
Received: June 25, 2010

Dear Mr. Meyer:

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.

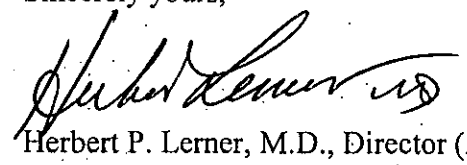
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101141

Indications for Use Form

AUG - 6 2010

510(k) Number (if known): K101141

Device Name: Seiler Colposcopes-Models 935, 955, & 985

Indications for Use:

The Seiler Colposcope is intended to provide magnified visualization of the tissues of the vulva, vagina, cervix and anogenital area. It is used to evaluate these tissues select areas for biopsy, as necessary, and to facilitate related procedures, e.g., LEEP conization, etc.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101141