OCT 19 1998

K981958

510(k) SUMMARY
FOR
LEISEGANG VIDEO COLPOSCOPE

1. SPONSOR/APPLICANT NAME, ADDRESS, TELEPHONE NUMBER

Leisegang Medical, Inc.
6401 Congress Avenue
Boca Raton, Florida
Telephone (561) 994-0202
Facsimile (561) 994-6603

Contact Person:

Debbie Iampietro
Director of Quality Assurance

Date of Summary Preparation:

June 3, 1998

2. DEVICE NAME

Proprietary Name:	Leisegang Video Colposcope
Common/Usual Name:	Colposcope
Classification Name:	Colposcope and Accessories

3. IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) TO WHICH EQUIVALENCE IS BEING CLAIMED

Leisegang Model 1D Colposcope, manufactured by Leisegang Medical, Inc., K940094 and the Model 88000 and 89000 Video Colposcopes, manufactured by Welch Allyn, Inc. K955635.

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4. DEVICE DESCRIPTION

The Galileo Leisegang Video Colposcope is intended for magnified viewing of the tissues of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The image can be viewed only on a color monitor.

The Leisegang Video Colposcope consists of a CCD camera with a halogen light source, green filter and is mounted on a mobile base.

5. INTENDED USE

The Leisegang Video Colposcope is intended for magnified viewing of the tissues of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The image can be viewed on a color monitor.

6. A STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) CITED

The Galileo, Leisegang and Welch Allyn Colposcopes are all intended to permit viewing and imaging of the tissues of the vagina and cervix to diagnose abnormalities and select areas for biopsy. While the predicate Leisegang devices are video adaptable, the Welch Allyn and the proposed Galileo Leisegang devices contain integrated imaging systems. These imaging systems provide the physician with a means to record pictures of the tissues for review over time.

All three devices function as non-patient contacting Colposcopes with working distances of 250 to 307 mm. The proposed Leisegang and the predicate Leisegang devices are standard Colposcopes in that the tissue is magnified and viewed directly via binocular microscopes with the option of using a video monitor. Operation of the Welch Allyn device differs in that the target image is always projected onto a video monitor rather than viewed directly through eyepieces.

All three devices have imaging capabilities. The predicate Leisegang Colposcopes have a video adaptor to allow for recording of the examination procedure. The video system of the proposed Galileo Leisegang and the Welch Allyn colposcopes are integral to its operation as the tissue can only be viewed by way of the video

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monitor. A VCR/Video Printer can be used to produce hard copies of images obtained using both the proposed and predicate Leisegang and Welch Allyn Colposcopes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 1998

Ms. Debbie Iampietro
Director of QA/RA
Galileo Corporation
Galileo Park
P.O. Box 550
Sturbridge, MA 01566

Re: K981958
Galileo Corporation Leisegang Video Colposcopes
Dated: September 10, 1998
Received: September 11, 1998
Regulatory Class: II
21 CFR 884.1630/Procode: 85 HEX

Dear Ms. Iampietro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981958

Device Name: Leisegang Video Colposcope

Indications For Use:

The Leisegang Video Colposcope is intended for magnified viewing of the tissues of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The image can be viewed only on a color monitor.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981958 /S001

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)