K021153

510(k) Summary

FEB 10 2003

1. Submitter's Identifiction:

Intellectual Property Law Group LLP
12 South First Street, 12th Floor
San Jose, CA 95113

Contact:

Y. Justin Chen
Attorney

Date:

2. Name of Device:

Device Name:

Goldway SLC-2000 Digital Video Colposcope Imaging System

Trade/ Proprietary Name:

Goldway SLC-2000 Digital Video Colposcope Imaging System

Common Name:

Colposcope

Classification:

21 CFR884.1640	Colposcope	85HEX	Class II

3. Pedicate Device Information

Identification of Legally Markted Device Which We Claim Substantial Equivalence (Predicate Device):

1. Leica Colposcopes, MS-5 and MZ-6, K#000707, Leica Microscopy Systems Ltd., Depew, New York.
2. Leisegang Video Colposcope (LMZ), K#940094, Leisegang Medical, Inc., Boca Raton, Florida
3. Welch Allyn Video Colposcope, 88000 and 89000, K#955635, Welch Allyn, Inc.

4. Device Description

a. Executive Summary:

The Goldway Digital Video Colposcope Imaging Systems, SLC-2000A and SLC-2000B are intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy.

The SLC-2000A consists of a ¼" Super HAD CCD color camera and image management workstation. Tissue is magnified and viewed directly either via a 5.6" LCD screen attached to the capture device or on the 14" color monitor attached to the image workstation. The SLC-2000B contains the same capture device but does not include the image workstation. Images can only be viewed via the 5.6" LCD screen with this model. The images provide recorded documentation for the physician or nurse practitioner to review for diagnostic purposes. The Goldway Colposcopes have a non-patient contact of up to 350mm. Both colposcopes have the option of being equipped with a Dermatology and Venereal Disease application kit and Dynamic White Polarization kit.

b. Device Description:

The Goldway Colposcopes, SLC-2000A and SLC-2000B are a non-patient contacting CCD color camera with a magnification of x1 ~ x28, working distances supporting 150-350mm, and a green filtered light source mounted on a floor stand. The SLC-2000B also comes with an image workstation which consists of a CCD camera, computer, LCD monitor, a mouse, a keyboard and color printer. The functions of the image management workstation include:

- Storing digital images for viewing during the colposcopy exam, and for printing and/or later review
- Storing textual information about a patient's medical history related to colposcopy
- Storing textual information about observations seen during a colposcopy examination
- Printing a colposcopy report that integrates images and textual information

5. Intended Use:

The Goldway Digital Video Colposcope Imaging System are intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The image system is intended to provide documentation of the image in the field of view of the colposcope. The image can be viewed on a color screen, printed on a color printer or archived for storage and subsequent retrieval. The device is intended to be used in Hospitals and clinics.

6. Comparison to Predicate Devices:

The Goldway, Leica, Leisegang and Welch Allyn Colposcopes are all intended to permit direct viewing and imaging of the tissues of the vagina, cervix and external genitalia to diagnose abnormalities and select areas for biopsy. The Goldway and Welch Allyn devices are both fully self-contained, stand-alone units incorporating light, power and video into a compact system. All predicate colposcopes provide for similar video capture and display functions that provide the necessary working distances required for patient observation. These imaging systems provide the physician/nurse practitioner with a means to record pictures of the tissues for review over time. All devices are offered with similar floor and table mounting stands.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following Standards were met:

- IEC60601-1
- ISO9001
- EN46001

8. Discussion of Clinical Tests Performed:

Not Applicable.

Conclusions

The Goldway Colposcopes have the same intended use and similar technological characteristics as the predicate devices. Moreover, the non-clinical testing and the preicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Goldway Colposcope is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2003

Goldway US, Inc.
c/o Mr. Y. Justin Chen
Intellectual Property Law Group, LLP
Old Bank of America Building
12 South First Street, 12th Floor
SAN JOSE CA 95113

Re: K021153
Trade/Device Name: Goldway SLC-2000 Digital Video Colposcope Imaging System
Regulation Number: 21 CFR §884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: 85 HEX
Dated: November 6, 2002
Received: November 12, 2002

Dear Mr. Chen:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021153

Device Name: GOLDWAY SLC-2000 DIGITAL VIDEO COLPOSCOPE IMAGING SYSTEM

Indications For Use:

The Goldway Digital Video Colposcope Imaging System is intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The image system is intended to provide documentation of the image in the field of view of the colposcope. The image can be viewed on a color screen, printed on a color printer or archived for storage and subsequent retrieval. The device is intended for use in Hospitals and clinics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021153