510(k) summary

MAR 10 2011

1. Submitter Identification

Submitter	Forth Photonics, Ltd Alba Innovation Centre Livingston, Scotland UK
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Date Prepared	02/04/2011

2. Device Identification

Name of Device	DySIS
Trade/Proprietary Name	DySIS
Common or Usual Name	Digital Colposcope
Classification	Colposcope (21CFR884.1630)
Product Code	85HEX

3. Predicate Devices

Manufacturer	Model	Trade Name	510(k)
Welch-Allyn	88000/8900	Video Colposcope	K955635
Cooper Surgical		CooperSurgical Digital Colposcopy System	K972630
Goldway	SLC-2000	Goldway Digital Video Colposcope Imaging System	K021153

The indications for use for Forth Photonics DySIS digital colposcope are substantially equivalent to the indications for use of the predicate devices.

4. Executive Summary

DySIS is a digital colposcope intended to provide magnified viewing of the vagina, cervix and external genitalia. DySIS is used to diagnose abnormalities and select areas for biopsy. DySIS acquires, displays and documents high-resolution still and sequentially

captured images and videos and provides color-coded mapping of the acetowhitening effect to facilitate assessment and documentation.

5. Device Description

DySIS offers non-patient contact, fully digital and high-resolution imaging of the cervix. The field of view is illuminated by an LED; a CCD camera coupled with the imaging optics provides crisp magnified color images. The images can be viewed on a color monitor and on the color touch screen that provides the means to control the device operation.

DySIS offers digital tools to fully document the colposcopic examination:

- Capturing of images for review, storage and printing, video recording
- Advanced magnification and imaging
- Operator's annotation of suspicious sites
- Color-coded mapping of acetowhitening intensity and duration
- Database that allows storing and retrieving identification and examination data

6. Indications for Use statement

DySIS with Pseudo-Color Imaging (PCI) is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification. Colposcopy is indicated for women with an abnormal Pap smear in order to affirm normality or detect abnormal appearances consistent with neoplasia, often with directed biopsy. The PCI feature is an adjunctive tool for displaying areas of acetowhitening. It is a tool that should NOT be used as a substitute for a thorough colposcopic evaluation.

7. Comparison to predicate devices

The CooperSurgical, Welch-Allyn and Goldway colposcopes permit magnified viewing of the tissues of the vagina, the cervix and external genitalia to identify atypical sites and select sites to biopsy. The Welch-Allyn and Goldway colposcopes feature viewing exclusively via a monitor, whereas the CooperSurgical colposcope also allows direct viewing. These systems also provide documentation capabilities, such as still image and/or video capture (all three) and reporting of the colposcopic predictions

(CooperSurgical and Goldway) and annotation/measurement tools (CooperSurgical). Further, DySIS offers optional color-coded mapping of acetowhitening by processing digital images, in a way similar to that of other medical devices. The DySIS color-coded mapping feature does not interfere with the view of the cervix during the colposcopic exam. It provides the colposcopist with an alternative representation and enhancement of the images captured during the acetowhitening effect. Specifically, the pseudocolor map depicts the extent, intensity and duration of the acetowhitening effect; however, it is not intended to automate the acetowhitening evaluation.

Use of the PCI feature is NOT a substitute for the conventional colposcopic view. When using the DySIS with Pseudo-Color Imaging (PCI) the clinician must ALWAYS first conduct a thorough colposcopic exam and identify and select areas for biopsy. The clinician may then use the Pseudo-Color Imaging (PCI) feature to (possibly) identify one or more additional biopsy sites, but may NEVER cancel any of the biopsy sites initially identified with the conventional colposcopic view.

DySIS is a fully digital colposcope, integrating a high-resolution CCD sensor, LED illumination and additional options to improve ergonomics and documentation of the colposcopic examination.

The provided technical improvements do not raise any questions of safety or effectiveness.

8. Non-Clinical Tests Supporting Substantial Equivalence

DySIS has undergone extensive testing to show substantial equivalence to existing colposcopes. The following tests have been performed:

a) LED temperature: Thermal output was measured on a piece of white paper placed at working distance. The temperature at the middle of the paper was measured with two instruments. The paper did not experience any significant increase in temperature after one hour of continuous exposure.

b) Timing Tolerance: This experiment tested the effect of two delay scenarios. The first, imaging delay, occurs when there is a delay between the time of acetic acid delivery and the start of imaging. The second, acetic acid delay, occurs when imaging is

started before acetic acid delivery. In both cases, differences from AUC values where no delay occurred were small and not statistically significant.

c) Acetic acid concentration: This experiment tested the difference in aceto-whitening between 3% and 5% acetic acid solutions. As expected the 5% solution exhibited a more extreme aceto-whitening effect. Overall, the experiment indicated that the DySIS map is capable of accurately depicting the aceto-whitening effect regardless of whether a 3% or 5% acetic acid solution is used.

d) Color Calibration: This tested the effects of moving the calibration test card closer or further than the standard focusing distance of 30 cm. An operator was asked to focus from a random distance between ±3 mm from focusing distance. The results indicated that Pixel Value (a function of reflected LED brightness) fell within the desired tolerance band of ±2 from points within this range.

e) Image Alignment: In order to test the effectiveness of the alignment algorithm, which is used to account for small movements during the exam, one cervical image was sequentially distorted ten times. The distortions totaled a 20% change from the original, which is equivalent to 7 mm of actual movement. The algorithm was able to compensate to 0.4 mm, well within the acceptable level.

9. Clinical Tests Supporting Substantial Equivalence

No clinical studies were conducted to demonstrate improved clinical performance using the PCI feature.

Test results using patient data indicate that the device meets performance specifications related to image registration, acetic acid timing errors, and range of PCI values.

Importantly, the study using retrospective patient data did not demonstrate that the PCI feature is superior to conventional colposcopy in helping the clinician target sites with suspected CIN for biopsy. Therefore, use of the PCI feature is not a substitute for conventional colposcopy. Consequently, the device is designed so that the clinician must perform a standard colposcopy and identify sites for biopsy before he/she can view the PCI image.

The device labeling clearly states that before viewing the PCI image, the clinician should ALWAYS perform colposcopy and commit to biopsy sites on the basis of the colposcopic evaluation. Labeling also states that colposcopically-directed biopsy sites should NEVER be cancelled on the basis of the PCI image

10. Conclusion

The Forth Photonics DySIS digital colposcope has equivalent indications for use and principles of operation to the referenced predicate devices. The additional features of the DySIS digital colposcope over the predicate devices do not raise any questions of safety and effectiveness. Thus, the DySIS digital colposcope is substantially equivalent to legally marketed colposcopes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Forth Photonics Hellas SA
% Ms. Amy Aulwes
Vice President
Health Policy Associates, Inc.
690 Canton Street, Suite 302
WESTWOOD MA 02090

MAR 10 2010

Re: K092433
Trade Name: DySIS Digital Colposcope
Regulation Number: 21 CFR §884.1630
Regulations Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: January 4, 2010
Received: January 5, 2010

Dear Ms. Aulwes:

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

Indications for Use

510(k) Number (if known): **K092433**

Device Name: **DySIS Digital Colposcope**

Indications for Use:

DySIS with Pseudo-Color Imaging (PCI) is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification. Colposcopy is indicated for women with an abnormal Pap smear in order to affirm normality or detect abnormal appearances consistent with neoplasia, often with directed biopsy.

The PCI feature is an adjunctive tool for displaying areas of acetowhitening. It is a tool that should NOT be used as a substitute for a thorough colposcopic evaluation.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K092433