5 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

1. General Information

Submitter's Name and Address:

STI Medical Systems, LLC
4275 Executive Square, Suite 825
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Contact Person and Telephone Number:

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Senior Vice President
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(808) 540-4728

Date Prepared: January 12, 2011

2. Device Information

Trade/Device Name:	UltraSightHD™ C31 Digital Colposcopy System with ImageSense™ and Remote Viewer Telemedicine Technologies
Classification Name:	Colposcope
Classification Regulation:	21 CFR § 884.1630
Regulatory Class:	Class II
Product Code:	HEX

3. Predicate Device(s):

- K090324, UltraSightHD (C30) Digital Colposcopy System with ImageSense Technology, STI Medical Systems, December 20, 2010.

4. Device Description:

The UltraSightHD™ C31 Digital Colposcopy System with ImageSense™ and Remote Viewer Telemedicine Technologies represents a modification to the UltraSightHD (C30) Digital Colposcopy System with ImageSense Technology. It is a digital colposcope designed to acquire images of the vagina, cervix and external genitalia. It is used to diagnose abnormalities and select areas for biopsy. The illumination and optical design of the device enable the user to capture high resolution digital images. The optical subsystem is augmented by integrated image quality assessment algorithms, ensuring that focused, centered, and balanced-contrast images are acquired. Two liquid crystal displays (LCDs) provide video display and user interface information. The software includes functionality for annotating, filtering and storing the images on external PACS servers via the DICOM protocol. The ImageSense™ filters highlight certain

characteristics of the captured images. The Remote Viewer Telemedicine feature enables medical personnel to view live video of an ongoing medical exam from a remote viewing station.

5. Indications for Use:

UltraSightHD™ C31 with ImageSense™ and Remote Viewer Telemedicine 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.

OpacityViewer™ is an ImageSense™ digital filter for displaying areas of acetowhitening. It is a tool that should NOT be used as a substitute for a thorough colposcopic evaluation. The Remote Viewer Telemedicine Technology is a software feature that enables medical personnel to view live video from the UltrasightHD during an ongoing medical exam from a remote viewing station.

6. Comparison of Technological Characteristics:

The materials and technologies in the UltraSightHD™ C31 Digital Colposcope are suitable for their intended use and are entirely similar to those of the predicate device. The addition of the remote viewing capability allows a computer at a different location to securely connect with the device to view the same imagery visible on the colposcope.

7. Testing:

Appropriate risk analysis-driven product testing was conducted to evaluate conformance to product specification. Successful compliance testing in accordance with IEC 60601-1 and 60601-1-2 (Safety and EMC) was conducted. The device is not patient contacting and therefore no biocompatibility testing was required.

8. Conclusion:

The UltraSightHD™ C31 Digital Colposcopy System with ImageSense™ and Remote Viewer Telemedicine Technologies is equivalent to the UltraSightHD™ (C30) Digital Colposcopy System with ImageSense™ Technology. The indications for use, safety and efficacy, basic overall design and function, product performance, and materials used are equivalent. The addition of the remote viewer does not affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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APR - 8 20[illegible]

Re: K110147
Trade Name: UltraSightHD™ C31 Digital Coloposcopy System with ImageSense™ and Remote Viewer Telemedicine Technologies
Regulation Number: 21 CFR §884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: January 12, 2011
Received: January 18, 2011

Dear Dr. Wolters:

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): K110147

Device Name: UltraSightHD™ C31 Digital Colposcopy System with ImageSense™ and Remote Viewer Telemedicine Technologies

Indications For Use:

UltraSightHD™ C31 with ImageSense™ and Remote Viewer Telemedicine 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.

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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 K110147