K102949

510(k) Summary

Colonoscopy Assistant™

JUN 15 2011

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
99-193 Aiea Heights Dr., Suite 136
Aiea, Hawaii 96701
USA

Contact Person and Telephone Number:

Rolf Wolters, Ph.D.
Senior Vice President
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(808) 540-4728

Date Prepared: September 30, 2010

2. Device Information

Trade/Proprietary Name:	Colonoscopy Assistant™
Common/Usual Name:	Colonoscope Electronic Media System
Classification Name:	Endoscopic Video Imaging System/Component
Classification Regulation:	21 CFR 876.1500
Device Class:	Class II
Product Code:	FET
Advisory Panel:	Gastroenterology-Urology

3. Predicate Device:

Karl Storz AIDA with DICOM and HL7 Interface (K043324)

4. Device Description:

Colonoscopy Assistant is a software application designed to provide a streamlined clinical user interface for colonoscopy. The software serves as a portal to useful information before, during, and after a colonoscopic exam. The software displays live video from the colonoscope, enables high-resolution image capture, provides digital noise reduction, displays side-by-side playback of previous exams, estimates the scope camera location during a colon video, and stores all patient and exam information.

5. Indications for Use:

This software is an accessory to standard colonoscopy. It is intended for use in the viewing, recording, archival, localization, documentation, and retrieval of still images, video, and patient data during and after a standard colonoscopic procedure. Standard colonoscopy is indicated for the evaluation of results from an abnormality on barium enema or other imaging study, unexplained gastrointestinal bleeding, screening and surveillance for colonic neoplasia, the excision of a colonic polyp, or the management of chronic inflammatory bowel disease.

Captured, compressed videos from previous exams are for viewing and reference purposes and are not intended for primary diagnosis.

6. Comparison of Technological Characteristics:

The *Colonoscopy Assistant* and the predicate device are both systems that enable viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic procedures.

The following table highlights similarities in technological characteristics between the proposed device and the predicate device:

	STI Colonoscopy Assistant	**Karl Storz AIDA / DICOM / HL7**
Software-based Technology	Yes	Yes
PC Hardware Platform	Required	Included
Video Digitizer Card	Required	Included
Captures Still Imagery	Yes	Yes
Records Video	Yes	Yes
Stores Patient and Exam Information along with Imagery	Yes	Yes

7. Nonclinical Testing:

The software device was verified and validated against the system requirements. V&V test procedures were created and executed on the software using an NTSC analog video input source. The results were compiled into V&V test reports. Furthermore, the planned risk mitigations in the hazard analysis were verified. This testing validates both the safety and efficacy of the software device.

The image noise reduction feature was verified specifically to ensure that the algorithm produced safe and effectiveness results on exam-specific imagery. For this purpose, colon images were processed to verify the image noise is decreased without adding image artifacts and the filtering results are reproducible.

8. Clinical Testing:

N/A

9. Conclusion:

The Indications for Use and technological characteristics of *Colonoscopy Assistant*™ are entirely similar to that of the predicate device. Furthermore, the proposed device raises no new issues of safety or effectiveness, as evidenced by verification and validation testing. Therefore, the *Colonoscopy Assistant* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Rolf Wolters, Ph.D.
Senior Vice President
STI Medical Systems, LLC
99-193 Aiea Heights Drive
AIEA HI 96701

JUN 15 2011

Re: K102949
Trade/Device Name: Colonoscopy Assistant
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: June 13, 2011
Received: June 13, 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.

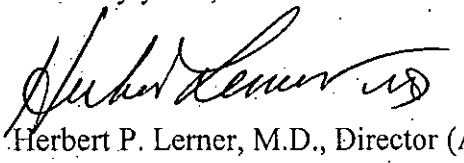
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

4 Indications for Use Statement

510(k) Number (if known): K102949

Device Name: Colonoscopy Assistant

Indications for Use: This software is an accessory to standard colonoscopy. It is intended for use in the viewing, recording, archival, localization, documentation, and retrieval of still images, video, and patient data during and after a standard colonoscopic procedure. Standard colonoscopy is indicated for the evaluation of results from an abnormality on barium enema or other imaging study, unexplained gastrointestinal bleeding, screening and surveillance for colonic neoplasia, the excision of a colonic polyp, or the management of chronic inflammatory bowel disease.

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K102949