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MAY 29 2009

KARL STORZ ENDOSCOPY

510(k) SUMMARY

Sponsor/Submitter: Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600
Phone: (310) 338-8100
Fax: (310) 410-5519

Contact Person: Crystal Dizol
Regulatory Affairs Specialist
Email: cdizol@ksea.com

Date of Submission: December 5, 2008

Device Trade Name: Karl Storz VOICE1® SCB R-UI Speech Control Application

Common Name: Endoscopic central control unit

Classification Name: Endoscope and accessories

Regulation Number: 21 CFR 876.1500

Product Code: ODA

Predicate Device(s): Karl Storz SCB R-UI Speech Control Option SCO (K003113)

Device Description: The Karl Storz VOICE1® SCB R-UI Speech Control Application is an independent application that works in the background of the SCB R-UI. VOICE1® recognizes commands spoken by the user and sends corresponding commands to the SCB R-UI system, enabling the user to control endoscopic and other ancillary surgical equipment and adjust device parameters entirely by speech control.

Indications for Use: The Karl Storz VOICE1® SCB R-UI Speech Control Application is indicated for use in speech control of Karl Storz-approved devices and peripherals in conjunction with the Karl Storz SCB® R-UI software.

Technological Characteristics: The Karl Storz VOICE1® SCB R-UI Speech Control Application is software designed for use with the Karl Storz OR1® Control Computer and Karl Storz SCB R-UI software. VOICE1 has a speech recognition component, a software bus, and graphical and auditory user interfaces.

Summary of Subtantial Equivalence: The Karl Storz VOICE1® SCB R-UI Speech Control Application is substantially equivalent to the predicate device since the basic functions, user interactions, and device types controlled are similar. The minor differences between the Karl Storz VOICE1® SCB R-UI Speech Control Application and the predicate device raise no new issues of safety and effectiveness. For a comparison between the Karl Storz VOICE1® SCB R-UI Speech Control Application and the predicate device, refer to the attached substantial equivalence chart.

Att: Substantial Equivalence Table for Karl Storz VOICE1® SCB R-UI Speech Control Application

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SUBSTANTIAL EQUIVALENCE TABLE FOR KARL STORZ VOICE1® SCB R-UI SPEECH CONTROL APPLICATION

Device	Karl Storz VOICE1® SCB R-UI Speech Control Application	Karl Storz SCB R-UI SCO (K994348)
Device Type	Software to provide voice control of SCB networked devices	Software to provide voice control of SCB networked devices
User Input	Microphone, Touch-screen	Microphone, Touch-screen
Devices Controlled	Light sources: *Xenon 175, Xenon 300* Cameras: *Image1* Insufflators: *Electronic Endoflator, Thermoflator* Documentation Systems: *AIDA 2.x, AIDA DVD-M, AIDA Compact II* Environmental Devices: *Media Control (Room Light, Surgical Light, Telephone)*	Light sources: *Xenon 175, Xenon 300* Cameras: *Tricam SL, Telecam SL* Insufflators: *Electronic Endoflator, Thermoflator* Image processors: *Reverse Video* Pumps: *Hamou Endomat, Hamou Micro-Hysteroflator, Uropump, Unimat 45* Lithotriptors: *Calcusplit*
Added Functions	No new functions added to controlled devices	No new functions added to controlled devices
Other Software Requirements	SCB R-UI Software must be installed	SCB R-UI Software must be installed
Intended use	For use in conjunction with Karl Storz SCB R-UI software to provide speech control of compatible devices connected to the SCB network	For use in conjunction with Karl Storz SCB R-UI software to provide speech control of compatible devices connected to the SCB network

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Crystal K. Dizol
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
EL SEGUNDO CA 90245

MAY 29 2009

Re: K083598
Trade Name: VOICE1® SCB R-UI Speech Control Application
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODA
Dated: May 25, 2009
Received: May 27, 2009

Dear Ms. Dizol:

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 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.

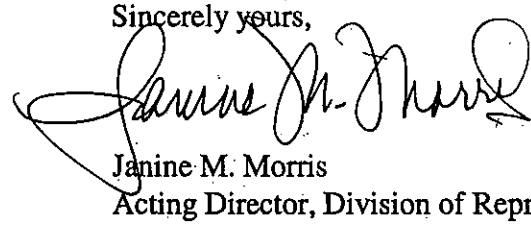
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not yet assigned

Device Name: Karl Storz VOICE1® SCB R-UI Speech Control Application

Indications for Use: The Karl Storz VOICE1® SCB R-UI Speech Control Application is indicated for use in speech control of Karl Storz-designated devices and peripherals in conjunction with the Karl Storz SCB® R-UI software.

Prescription Use: ✓ AND/OR Over-The-Counter Use: _____
(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, Abdominal, and Radiological Devices
510(k) Number K083598