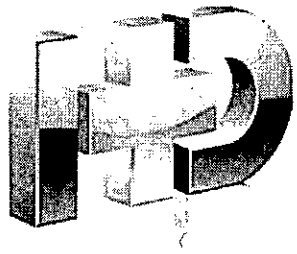


HD Medical Services (India) Private Ltd

48, Industrial Estate
IT Highway, Perungudi
Chennai, 600096, India
Tel: +91 44 4215 4771
Fax: +91 44 4215 4772
www.hdmedicalgroup.com

Summary of Safety and Effectiveness

ViScope Electronic Stethoscope

SUBMITTER INFORMATION

Company Name: HD Medical Services (India) Pvt. LTD.

Company Address: No. 48, Perungudi Industrial Estate
IT Highway
Perungudi, Chennai
ZIP - 600096

Company Phone: +91 44 4215 4771

Company Fax: +91 44 4215 4772

Contact Persons: S. Subramaniam
Manager- Quality Management

Date Summary Prepared: January 26, 2010

DEVICE IDENTIFICATION

Common or Usual Name:	Electronic Stethoscope, Cardiogram
Trade/Proprietary Name:	ViScope
Classification:	Class II, 21 CFR 870.1875, 870.2390
Product Code:	DQD, DQC
Performance Standard :	**None**

PREDICATE DEVICES:

- CADI Tech AG CADIscope electronic ECG Stethoscope, K990809 Dated 09/21/199
- 3M Healthcare Littman Electronic Stethoscope, Model 3200 with Zargis Sethassist Software, K083903 Dated 07/15/09 and K090493 Dated 08/07/2009

DEVICE DESCRIPTION

The ViScope Electronic Stethoscope (ViScope) is an audio-visual auscultation tool for quick and effective auscultation of a patient to aid the healthcare professional as necessary during patient care and/or for triage purposes. The ViScope is a **Visual Phono Cardio Gram** (VPCG) with visual display on which the heart sounds are represented as waveforms, which medical practitioners recognize and understand. The ViScope, similar to most electronic stethoscopes, has switchable modes (Bell/Dia/wide) for hearing heart, lung, blood vessel, enteral and other body sounds with different frequency ranges. In addition, the ViScope has an incorporated 'memory' feature that provides the user with the ability to review the saved 4 waveforms. The user also has the option to delete each waveform individually.

The ViScope comes in two models, the ViScope 100S and the ViScope 100P. The models are the same device (design, technology, operation, manufacture, use, labeling, etc). The only difference is that the ViScope 100P has the ability to download data to a PC or printer, the ViScope 100S does not offer this download feature. The ViScope 100P is supported by software that can be installed in a PC. The user can see the real-time waveforms on the PC monitor (as live data) and record in 10 second intervals. The software allows the user with an option of selecting the entire 10 second signal or select

any 3.5 seconds within the 10 second signal for a more detailed view. These selected signals can be saved with patient name, auscultation region, along with age & sex. The software tools such as zoom, calipers, and player functions can be used on the saved signals for further analysis. The saved signals can be printed from the PC or directly from the ViScope 100P.

INDICATIONS FOR USE

The ViScope is a patented electronic stethoscope with an integrated graphics display to show amplified heart sounds as phonocardiograms. It is intended for use as a diagnostic aid as part of a physical assessment of a patient by health care professionals or other individuals trained to administer emergency first aid or otherwise care for a patient. It can be used for the amplification of heart, lung, blood vessel, enteral and other body sounds.

SUBSTANTIAL EQUIVALENCE

The ViScope is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared	SE Component
CADIscope Electronic ECG Stethoscope	CADI Tech AG	K990809	9/21/1999	-Indications for Use -Visual Display -General Operation
3M Littman * Model 3200 Electronic Stethoscope with Zargis Sethassist Software*	3M Healthcare	K083903 K090493	07/15/09 08/07/09	-Indication for Use -Download capabilities -General Operation

* The two devices are sold as a package.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ViScope and the predicate devices has been performed. The results of this comparison demonstrate that the ViScope is substantially equivalent to the marketed predicate devices in technological characteristics and performance requirements.

PERFORMANCE DATA and CONCLUSION: The performance data indicate that the Viscope meets specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

HD Medical Services PVT., LTD.
c/o Mr. William H. Murphy
Murphy & Associates
11143 Twinleaf Way
San Diego, CA 92131

JUL 21 2010

Re: K100531
Trade/Device Name: ViScope Electronic Stethoscope (models 100P and 100S)
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD, DQC
Dated: July 13, 2010
Received: July 14, 2010

Dear Mr. Murphy:

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.

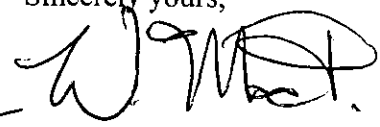
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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.

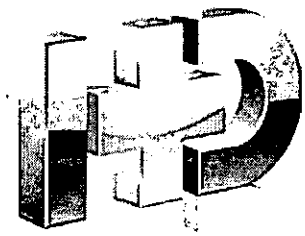
You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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510(k) Number : K100531

Device Name: ViScope Electronic Stethoscope

JUL 21 2010

Indications for Use Statement:

The ViScope Electronic Stethoscope is a patented electronic stethoscope with an integrated graphics display to show amplified heart sounds as phonocardiograms.
It is intended for use as a diagnostic aid as part of a physical assessment of a patient by health care professionals or other individuals trained to administer emergency first aid or otherwise care for a patient. It can be used for the amplification of heart, lung, blood vessel, enteral and other body sounds.

Prescription Use Yes (Part 21 CFR 801 Subpart D)	AND	Over-The-Counter Use No (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 Cardiovascular Devices

510(k) Number K100531

1 of 1