



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 12 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Einar Heiberg
President, CEO
Medviso
Thulehemsvagen 157
Lund SE-224 67
SWEDEN

Re: K090833

Trade/Device Name: Segment / Image Processing System

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: March 18, 2009

Received: March 26, 2009

Dear Mr. Heiberg:

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.

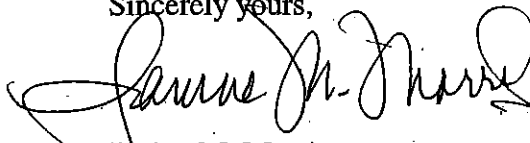
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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

4 Indications for Use

Indications for Use Statement

510(k) Number (if known): K090833

Device Name: Segment / Image Processing System

Indications For Use:

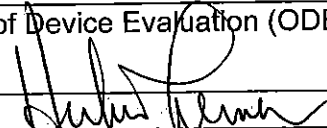
Segment is a software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. **Segment** specifically analyzes the function of the heart and its major vessels using multi-slice, multi-frame and velocity encoded MR images. It provides clinically relevant and reproducible data for supporting the evaluation of the function of the chambers of the heart such as left and right ventricular volumes, ejection fractions, stroke volumes, peak ejection and filling rates, myocardial mass, regional wall thickness, fractional thickening and wall motion. It also provides quantitative data on blood flow and velocity in the arterial vessels and at the heart valves. **Segment** is tested on MR images acquired from both 1.5 T and 3 T MR scanners. The data produced by **Segment** is intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making. **It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.**

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)
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(Division Sign-Off)
MEDVISO
Division of Reproductive, Abdominal and
Radiological Devices
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FDA 510(k) Submission
2009-05-11