DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 5, 2017

Medviso AB
% Einar Heiberg, Ph.D.
Founder, Vice President, CTO
Griffelvägen 3
Lund SE-224 67
SWEDEN

Re: K163076
Trade/Device Name: Segment CMR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 3, 2016
Received: March 14, 2017

Dear Dr. 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 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K163076

Device Name
Segment CMR

Indications for Use *(Describe)*
Segment CMR is a software that display and analyzes medical images in DICOM-format using multi-slice, multi-frame and velocity encoded MR images. Segment CMR provides features for analysis of cardiac function, such as cardiac pumping and blood flow. The ventricular analysis is provided for usage in both pediatric (from newborn) and adult population. Images and associated data analysis can be stored, communicated, rendered, and displayed within the system and across PACS system. The data produced by Segment CMR 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 5 510 (k) Summary

## 5.1 Submitter

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**Date Prepared:** October 1, 2016

**Contact Person:** Einar Heiberg, PhD, Founder, CTO, +46-76-1836442, einar@medviso.com

## 5.2 Device

**Device Trade Name:** Segment CMR

**Device Common Name:** Cardiovascular MRI analysis software

**Classification Name:** Class II – System, Image Processing

**Regulation Number:** 892.2050

**Product Code:** LLZ

## 5.3 Predicate Device

- Segment (K090833)
  Medviso AB
  Griffelvägen 3
  224 67 Lund
  Sweden

- CMRtools and plugins Ventricular tools and Thalassemia tools (K073194)
  Cardiovascular Imaging Solutions Ltd
  53 Cavendish Road
  London SW12 0BL
  UK

- Virtue including module HARP (K111833, K100352)
  Myocardial solutions
  1204 Village Market Pl 290
  Morrisville, NC 27560
  USA

## 5.4 Device Description

**Device Description**

***Segment CMR*** is a software that displays and analyzes multi-slice, multi-phase and velocity encoded DICOM compatible medical MR images. ***Segment CMR*** provides quantitative measures for analysis of function of the cardiovascular system. The data produced by ***Segment CMR*** is intended to be used to support qualified cardiologist, radiologist or other professional healthcare practitioners for clinical decision making. Functional, flow, valve, vessel, and tissue analysis is performed using standardized algorithms and user input. The quantification methods are validated and reproducible. The ventricular analysis is provided for usage in both pediatric (from newborn) and adult population.

MR images may be imported from various sources including images stored on portable media, network storage devices, and other vendor systems and supports cardiovascular MR images from all of the major MRI scanner vendors.

## 5.5 Intended Use

**Indications for Use**

**Segment CMR** is a software that display and analyzes medical images in DICOM-format using multi-slice, multi-frame and velocity encoded MR images. **Segment CMR** provides features for analysis of cardiac function, such as cardiac pumping and blood flow. The ventricular analysis is provided for usage in both pediatric (from newborn) and adult population. Images and associated data analysis can be stored, communicated, rendered, and displayed within the system and across PACS system. The data produced by **Segment CMR** 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.**

**Application Specification**

The medical purpose for ***Segment CMR*** is to analyze Cardiac Magnetic Resonance (CMR) images. Conditions or disease to be diagnosed by CMR imaging are heart diseases such as myocardial infarction, cardiac failure, cardiomyopathy and valvular disease.

**Patient Population**

***Segment CMR*** is intended for use in both pediatric population (from newborn to adolescent) and adult population.

**Comparison to Predicate Device**

Both ***Segment CMR*** and the predicate devices are support tools which provide the clinician with relevant clinical data to support diagnoses by analyzing CMR images. All analysis features provided by ***Segment CMR*** are also provided by one or more of the predicate device. The difference in the indications for use is the extension of the patient population to also include pediatric population for the ventricular analysis. According to validation in scientific publications and the risk management analysis for ***Segment CMR***, the inclusion of pediatric population does not affect the safety and effectiveness of the device.

## 5.6 Technological Characteristics

***Segment CMR*** and the predicate device are both software packages that can be used for the analysis of multi-slice, multi-frame and phase encoded DICOM-compliant MR image data sets. None of the devices comes into direct contact with the patient.

The proposed and predicate devices provide a user interface with items for selecting images and adjusting image viewing. They perform data analysis by using standardized algorithms and user inputs to delineate the myocardial and vascular walls from surrounding tissue and blood (wall contours). The proposed and predicate devices render wall contours either fully automatically, semi-automatically, manually or in combination providing clinically relevant data. The technological differences between ***Segment CMR*** and the predicated devices are that different algorithms in use for the automatic segmentation approaches and relaxometry measurements. The proposed and predicate devices can be operated from a personal computer. ***Segment CMR*** has substantially equivalent features and specifications to the predicate devices.

## 5.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

**Software Verification and Validation Testing**

Software verification and validation testing were conducted and documented according ty FDA's Guidance "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices". It was concluded that ***Segment CMR*** was considered as "moderate" level of concern. Extensive testing of the software package is performed by an automated test suite prior to commercial release, exactly like the predicate device Segment. As a complement to this, manual testing is performed by programmers and the program is evaluated by two beta test sites. In addition, the predicate device Segment, on which ***Segment CMR*** is built upon, is used by more than 200 research groups.

**Bench, Animal and Clinical Studies**

Each of the features for ***Segment CMR*** has been clinically evaluated by using both bench, animal and clinical studies. The studies are validation or application studies using establish methods as reference standard. Since the subject device is no treatment device there is no randomized control in the studies. The studies were performed in US or in Europe. Since the subject device is not intended to be used for treatment, the identification of primary safety endpoint and primary effectiveness endpoint are not applicable. The results by the studies show that the values from the evaluated features in ***Segment CMR*** were in good agreement with values from the reference method. No adverse advents or complications associated with the subject device were observed in the studies. Based on the clinical performance as documented in the performance studies, ***Segment CMR*** was found to have a safety and effectiveness profile that is similar to the predicate device.

## 5.8 Conclusion

We conclude that the subject device ***Segment CMR*** is as safe and effective as the predicate devices. All identified hazards for ***Segment CMR*** have been mitigated to accepted levels of the residual risk and the overall risk residual evaluation concluded that the risk of ***Segment CMR*** is acceptable. The risks associated with the use of ***Segment CMR*** are acceptable when weighted against the benefits of the patient. The extension of pediatric use for the left ventricular analysis did not, according to the hazard analysis, increase the overall residual risk and by evaluating safety and effectiveness, the benefits with pediatric use can be considered to outweigh the risks. ***Segment CMR*** performs in accordance with its intended use as well as the cardiovascular MRI image analysis products currently on the market. Identical to the predicate devices, ***Segment CMR*** does not in any way alter the MRI imaging data in the analytical process. ***Segment CMR*** provides assistance to a professionally trained physician and all of the information is subject to his/her oversight and control. Medviso AB considers the features of ***Segment CMR*** to be substantially equivalent to the subset of features in common with the predicate devices Segment, CMRtools and Virtue including module HARP.