



Food and Drug Administration
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Silver Spring, MD 20993-0002

Vidistar, LLC
% Ms. Kathryn Becker
Principal
Translational Science Solutions, LLC
92 Hasell Street #401
CHARLESTON SC 29401

November 25, 2015

Re: K152822
Trade/Device Name: Vidistar HeartView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: LLZ
Dated: September 29, 2015
Received: September 30, 2015

Dear Ms. Becker:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the typed name.

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

Enclosure

Indications for Use

510(k) Number (if known)

K152822

Device Name

VidiStar HeartView

Indications for Use (Describe)

The HeartView system is an internet-based application intended for use by nuclear medicine or radiology practitioners and referring physicians for the automated processing, review, quantification, and multidimensional review of nuclear medicine cardiology medical images, and specifically, radionuclides distributed in the body using planar and tomographic short axis images.

HeartView may be used in various clinical settings including a hospital, clinic, imaging center, physician office, or remote locations.

The HeartView system implements algorithms for automatic quantification of myocardial perfusion single photon emission computerized tomography (SPECT) as well as quantification of ejection fraction, wall motion, and thickening from gated myocardial perfusion SPECT images.

Gated results are presented as 3D plots that can be used to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes, including quantitative assessments of cardiac function (e.g., systolic and diastolic function, regional wall thickening, wall motion, transient ischemic dilation, and phase analysis).

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.

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510(K) SUMMARY

Submission Date: September 24, 2015

Submitter Information:

Submitted By: VidiStar, LLC
PO Box 8539
Greenville, SC 29604

Contact Person: Craig Walker, MHA
Chief Executive Officer
VidiStar, LLC
Tel: (512) 797-1910
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Device Information:

Trade Name: HeartView

Common Name: Nuclear Medicine Workstation

Classification Name: System, Image Processing, Radiological
21 CFR 892.2050

Regulatory Class: Class II

Product Code: LLZ

Predicate Device: Xeleris 3.1 Processing and Review Workstation (K130884)
GE Healthcare
Class II (21 CFR 892.2050; Product Code LLZ)

Device Description: The HeartView platform is a comprehensive internet-based application designed to process, review, and automatically perform quantitative analysis of cardiac nuclear medicine procedures. HeartView implements algorithms for automatic quantification of myocardial perfusion SPECT, as well as quantification of ejection fraction, wall motion, and thickening from gated myocardial perfusion SPECT. The algorithm takes short axis slices reconstructed from raw datasets of gated and averaged acquisitions in rest and stress, and operates in multi-dimension (3D), rather than processing individual slices separately. For gated datasets,

it processes the dataset as a whole rather than processing each frame separately, which adds additional knowledge to the algorithm for its computations, and allows enforcement of the constraint that the mid-myocardium volume is constant during the whole heart beat cycle.

Intended Use:

The HeartView software application is intended to provide an automated processing, review, quantification, and multidimensional review of nuclear medicine cardiology medical images, and specifically, radionuclides distributed in the body using planar and tomographic short axis images. HeartView may be used in various clinical settings including a hospital, clinic, imaging center, physician office, or remote locations. HeartView implements algorithms for automatic quantification of myocardial perfusion single photon emission computerized tomography (SPECT) as well as quantification of ejection fraction, wall motion, and thickening from gated myocardial perfusion SPECT images.

Indications for Use:

The HeartView system is an internet-based application intended for use by nuclear medicine or radiology practitioners and referring physicians for the automated processing, review, quantification, and multidimensional review of nuclear medicine cardiology medical images, and specifically, radionuclides distributed in the body using planar and tomographic short axis images.

HeartView may be used in various clinical settings including a hospital, clinic, imaging center, physician office, or remote locations.

The HeartView system implements algorithms for automatic quantification of myocardial perfusion single photon emission computerized tomography (SPECT) as well as quantification of ejection fraction, wall motion, and thickening from gated myocardial perfusion SPECT images.

Gated results are presented as 3D plots that can be used to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes, including quantitative assessments of cardiac function (e.g., systolic

and diastolic function, regional wall thickening, wall motion, transient ischemic dilation, and phase analysis).

Comparison to Predicate Device Technology:

The device and the predicate device are both image post processing workstations devices that provide similar features of visualization and quantitative analysis and do not raise any new questions of safety or effectiveness.

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 documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “moderate” level of concern, as a malfunction of, or a latent design flaw in, the software device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

Comparative Testing:

Comparative performance testing was conducted to demonstrate that the subject device is equivalent to the predicate device for the review of nuclear studies in terms of quantitative (software-calculated values) and qualitative (subjective clinical reading) output. To support this performance claim, anonymized patient imaging studies were compared quantitatively (precision utilizing statistical software) and qualitatively (clinical review by a blinded independent cardiologist) . The subject device was found to be comparable to the predicate device in terms of qualitative and quantitative output.

Additional Information:

Performance Standards:

The subject device is in compliance with the following voluntary performance and safety standards:

- NEMA PS 3.1 - 3.20 (2011) Digital Imaging and Communications in Medicine (DICOM) Set
- ISO/IEC 10918-1 First edition 1994-02-15 Information technology- Digital compression and coding of continuous-tone still images: Requirements and

guidelines [including: Technical Corrigendum 1 (2005)]

Other Standards:

The present 510(k) was prepared in consideration of the following guidance documents:

- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices (2000)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (2014)

Conclusion:

Based on conformance to FDA recognized voluntary consensus standards, development under applicable FDA guidance, and the extensive product testing described within this 510(k) premarket notification, VidiStar provides evidence that its HeartView system is as safe and effective, and performs in a substantially equivalent manner to GE Healthcare's Xeleris 3.1 Processing and Review Workstation.

