K130902

ITEM I

JUN 14 2013

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Syntermed, Inc.
Registration No. 1066019
Owner Operator I.D. 9041128
Device Regulation Number: 892.1200
Product Code: KPS
Classification Panel: Radiology
Voice: (888) 263-4446 ext 102, FAX: (714) 281-1290
Contact person: Kenneth F. Van Train
Address: Syntermed, Inc.
130 Wieuca Road
Suite 108
Atlanta, GA 30342

Email: vantrain@syntermed.com

Date Summary Prepared: March 29, 2013

2. Medical Device:

Emory Cardiac Toolbox™ 3.2 - Display and Processing program for gated SPECT & PET myocardial perfusion studies executing on nuclear medicine computer systems and Windows PC's.

Classification Name – System, Tomography, Computed, Emission

3. Medical Device Equivalence:

Emory Cardiac Toolbox v3.1, Reference#: K071503.

4. Device Description:

The Emory Cardiac Toolbox™ 3.2 is used to display gated wall motion and for quantifying parameters of left-ventricular perfusion and function from gated SPECT & PET myocardial perfusion studies. These parameters are: perfusion, ejection fraction, end-diastolic volume, end-systolic volume, myocardial mass, transient ischemic dilatation (TID), and cardiac mechanic dyssynchrony. In addition, the

program offers the capability of providing the following diagnostic information: computer assisted visual scoring, prognostic information, expert system image interpretation, and patient specific 3D coronary overlay. The program can also be used for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface and for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM). The Emory Cardiac Toolbox can be used with any of the following Myocardial SPECT Protocols: Same Day and Two Day Sestamibi, Dual-Isotope (Tc-99m/Tl-201), Tetrofosmin, and Thallium, Rubidium-82, N-13-ammonia, FDG protocols, and user defined normal databases. The program can also be used for the quantitative analysis and display of SPECT AdreView™ (^{123}I-*m*IBG) data sets. This program was developed to run in the IDL operating system environment which can be executed on any nuclear medicine computer systems which supports IDL and the Aladdin (General Electric) software development environment. The program processes the studies automatically, however, user verification of output is required and manual processing capability is provided.

5. Intended Use:

The intended use of this program was to provide the physician with a program which would allow him to determine quantitative analysis of the myocardial perfusion, display wall motion and determine measurements of ejection fraction and ventricular volumes from his patients gated SPECT & PET myocardial perfusion study, obtain visual interpretation scores, prognostic information, expert system interpretation, for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface, for the assessment of cardiac mechanic dyssynchrony using phase analysis, for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM), and for the quantitative analysis and display of SPECT AdreView™ (^{123}I-*m*IBG) data sets for evaluation of patients with congestive heart failure.

This program serves merely as a display and processing program to aid in the diagnostic interpretation of a patients' study. It was not meant to replace or eliminate the standard visual analysis of the gated SPECT & PET study. The physician should integrate all of the patients' clinical and diagnostic information, i.e. patients' history, stress and/or rest EKG, quality control images, visual interpretation of the gated tomographic images, and quantitative results, prior to making his final interpretation. This comprehensive processing technique (as with all diagnostic imaging) is not perfect, and will be associated with some false positive and false negative results. The expected accuracy of the initial program can be found in the multicenter trial results listed in the article by Vansant et al Emory Cardiac Toolbox™ (CEqual®, EGS™) Version 2.0, Ref. 510(k) #: K992450 and Version 2.1, Ref. 510(k) #: K014033). The accuracy and reproducibility for modifications in version 3.2 for the quantitative analysis and display of SPECT AdreView™ (^{123}I-

*m*IBG) data sets can be found in Item H (Testing & Validation) of this 510(k) submission. The physician should be aware of the accuracy when integrating the quantitative results for his final interpretation. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been several medical device gated SPECT programs marketed in the past which perform similar functions to those performed by the Emory Cardiac Tool Box™ 2.0, 2.1, 2.6, and 3.1. These programs are all used for the purpose of displaying wall motion and deriving functional parameters for the diagnostic interpretation by a physician. The Emory Cardiac Tool Box™ 3.2 provides additional features for the quantitative analysis and display of SPECT AdreView™ (^{123}I-*m*IBG) data sets and we believe is substantially equivalent to the T.I.D. and SyncTool™ analysis contained within our previous commercially released application Emory Cardiac Toolbox v3.1, K071503. To our knowledge there have been no safety problems with the T.I.D. or SyncTool™ applications in the Emory Cardiac Toolbox v3.1 which has been in the marketplace since July 26, 2007.

7. Performance Testing Summary

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the initial program, Emory Cardiac Toolbox™ 2.0, has been established in phantom and computer simulations studies, in-house trial validations which included an evaluation of left ventricular functional parameter calculations in 217 patients, and in a multicenter trial validation consisting of 80 patients. In addition, the computer assisted visual scoring, prognosis, expert system, and coronary fusion algorithms were successfully evaluated in 20, 504, 461, and 9 patients respectively. Additional validation of the Emory Cardiac Toolbox™ 2.1 program for development and validation of Rb-82 normal limits (n=176) and validation of PET tools for assessment of perfusion – metabolism match-mismatch (n=90) were successfully completed. Validation for the Emory Cardiac Toolbox™ 2.6 program included development and validation of N-13-ammonia normal limits (n= 144) and validation of the alignment method for 3D CT coronary artery onto the left ventricular 3D epicardial surface using phantom and patient studies (n = 8). Validation for the Emory Cardiac Toolbox™ 3.1 program included development (phantom, animal, and patients n=4) and prospective validation of SPECT reconstruction in 10 patients and for phase analysis (SyncTool™) which included development in 90 normal patients and prospective validation in 75 additional patients. The validation results for the Emory Cardiac Toolbox™ 3.2 program are listed in Item H, Testing & Validation. In summary, there were two groups of patients used in this study, a pilot group consisting of 67 patients who were used to develop the heart volume regions of interest on the SPECT reconstructions and a validation group consisting of 1,016 patients that were used to validate the heart-to-mediastinum (H/M) ratio method. The results obtained in our validation for SPECT demonstrated the capability to differentiate subjects with abnormal and normal AdreView™ uptake using the H/M ratio index.

8. Conclusions:

We contend that the method employed for the development and validation for the quantitative analysis and display of SPECT AdreView™ (^{123}I-*m*IBG) data sets in Emory Cardiac Toolbox™ 3.2, have proven its safety and effectiveness. In our opinion the additional features in Emory Cardiac Toolbox™ 3.2 for generation of a ratio index (H/M ratio) for AdreView™ studies which is used to evaluate patients with congestive heart failure is substantially equivalent to the methods used to generate the T.I.D. ratio index and the SyncTool application for evaluation of congestive heart failure patients currently available in Emory Cardiac Toolbox™ 3.1. The Emory Cardiac Toolbox™ 3.2 is intended for the same purpose as Emory Cardiac Toolbox™ 3.1 and raises no new issues of safety or effectiveness.

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

June 14, 2013

Syntermed, Inc.
% Kenneth Van Train, Ph.D.
President
245 South Owens Drive
ANAHEIM CA 92808

Re: K130902
Trade/Device Name: Emory Cardiac Toolbox™ 3.2
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography
Regulatory Class: Class II
Product Code: KPS
Dated: March 29, 2013
Received: April 11, 2013

Dear Dr. Van Train:

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 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. 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,

Michael D. O'Hara for

Janine M. Morris
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) K130902

Device Name: Emory Cardiac Toolbox™ 3.2

Indications for Use:

The Emory Cardiac Toolbox™ 3.2 software program should be used for the quantification of myocardial perfusion for the display of wall motion and quantification of left-ventricular function parameters from gated Tc^{99m} SPECT & PET myocardial perfusion studies (EGS™), for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface, for the assessment of cardiac mechanic dyssynchrony using phase analysis, for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM), and for the quantitative analysis and display of SPECT AdreView™ (^{123}I-*m*IBG) data sets used for evaluation of patients with congestive heart failure.

The product is intended for use by trained nuclear technicians and nuclear medicine or nuclear cardiology physicians. The clinician remains ultimately responsible for the final interpretation and diagnosis based on standard practices and visual interpretation of all SPECT and PET data.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130902