March 30, 2023

Syntermed
% Kenneth Van Train
President
245 South Owens Drive
ANAHEIM CA 92808

Re: K223422
Trade/Device Name: Emory Cardiac Toolbox™ 4.3
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK, LLZ
Dated: February 24, 2023
Received: March 1, 2023

Dear Kenneth 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223422

Device Name

Emory Cardiac Toolbox 4.3

Indications for Use *(Describe)*

The Emory Cardiac Toolbox™ 4.0 – 4.3 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 SPECT & PET myocardial perfusion studies (EGS™) including to quantitatively evaluate the wall motion and wall thickening of the heart using longitudinal, radial, and circumferential strain measurements, for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface and analysis of the CT data to evaluate calcified plaques in the coronary arteries, for the assessment of cardiac mechanical dyssynchrony using phase analysis, for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered back projection (FBP) or iterative reconstruction (MLEM/OSEM), for the quantification of myocardial blood flow and coronary flow reserve, and for the decision support in interpretation (LVX) and automatic structured reporting of the study.

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

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY
K223422

1. Identification of the Submitter:

Kenneth Van Train
President
Syntermed, Inc.
333 Sandy Springs Circle
Suite 107
Atlanta, GA 30328
Voice: (888) 263-4446 ext. 102, FAX: (714) 281-1290
Date of submission: January 3, 2022

2. Identification of the Product:

Device Proprietary Name: Emory Cardiac Toolbox™ 4.3
Common Name: Cardiac image processing software for SPECT and PET
Classification Name: Emission Computed Tomography System
Regulation Number: KPS: 21 CFR 892.1200, JAK: 21 CFR 892.1750, and LLZ: 21 CFR 892.2050
Product Code: KPS, JAK, and LLZ
Classification Panel: Radiology
Device Class: Class II

3. Medical Device Equivalence:

- Emory Cardiac Toolbox™ 4.0 K123646
- Syngo.CT Ca Scoring developed by Siemens Medical Solutions USA, Inc. K201034
- TOMTEC-Arena (AutoStrain Suite) developed by TOMTEC Imaging Systems GmbH K201632.

4. Device Description:

The Emory Cardiac Toolbox™ 4.3 is used to display gated wall motion and for quantifying parameters of left-ventricular perfusion and function from gated SPECT & PET myocardial perfusion studies and for the evaluation of dynamic PET studies.

5. New features in the current device

The new features added to the Emory Cardiac Toolbox™ are the analysis of the CT data to evaluate calcified plaques in the coronary arteries and analysis of wall motion and wall thickening of the heart using longitudinal, radial, and circumferential strain measurements.

6. Indication for Use

The Emory Cardiac Toolbox™ 4.0 – 4.3 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 SPECT & PET myocardial perfusion studies (EGS™) including to quantitatively evaluate the wall motion and wall thickening of the heart using longitudinal, radial, and circumferential strain measurements, for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface and analysis of the CT data to evaluate calcified plaques in the coronary arteries, for the assessment of cardiac mechanical 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), for the quantification of myocardial blood flow and coronary flow reserve, and for the decision support in interpretation (LVX) and automatic structured reporting of the study.

7. Comparison Table with predicate device(s)

Submitted Device: Emory Cardiac Toolbox™ 4.3 (K223422)
Predicate Devices:

- Emory Cardiac Toolbox™ 4.0 (K123646)
- Calcium Scoring: Syngo.CT Ca Scoring developed by Siemens Medical Solutions USA, Inc. (K201034)
- Strain Analysis: TOMTEC-Arena (AutoStrain Suite) developed by TOMTEC Imaging Systems GmbH (K201632)

Function or Parameter	ECTb™ 4.0	ECTb™ 4.3	Syngo.CT	TOMTEC-Arena
2D and 3D Display of perfusion and left-ventricular function from gated SPECT & PET myocardial perfusion studies	**Yes**	**Yes**	**NA**	**NA**
Quantitative analysis of perfusion for extent, severity, reversibility, mass, and viability	**Yes**	**Yes**	**NA**	**NA**
Quantitative analysis of function for ejection fraction, end-diastolic volume, end-systolic volume, myocardial mass volumes, wall thickening, and transient ischemic dilation (TID)	**Yes**	**Yes**	**NA**	**NA**
Provides computer assisted visual scoring and prognostic information	**Yes**	**Yes**	**NA**	**NA**
Decision support for image interpretation	**Yes**	**Yes**	**NA**	**NA**
3D alignment of coronary	**Yes**	**Yes**	**NA**	**NA**

artery models from CT coronary angiography onto left ventricular 3D epicardial surface				
Can be used with the following myocardial protocols: Same Day and two Day Sestamibi, Dual-Isotope (Tc-99m/Tl-201), Tetrofosmin, Thallium, Rubidium-82, N-13 Ammonia, and FDG	**Yes**	**Yes**	**NA**	**NA**
Provides automatic and manual reorientation of SPECT gated and non-gated data sets.	**Yes**	**Yes**	**NA**	**NA**
Measurement of Left ventricular dyssyncrony	**Yes**	**Yes**	**NA**	**NA**
Provides a method for analyzing Myocardial Blood Flow and Coronary Flow Reserve	**Yes**	**Yes**	**NA**	**NA**
Automatic highlighting of coronary calcifications. The calcified plaques are assigned manually to their respective coronary artery by mouse click.	**NA**	**Yes**	**Yes**	**NA**
Automatic highlighting of meta using a default threshold of 1000 HU.	**NA**	**Yes**	**Yes**	**NA**
Ability to calculate Agatston scores and plaque volumes	**NA**	**Yes**	**Yes**	**NA**
Automatic evaluation of lesions by a 3D segmentation algorithm	**NA**	**Yes**	**Yes**	**NA**
Ability to split a lesion into 2 territories.	**NA**	**Yes**	**Yes**	**NA**
Ability to window the Calcium Scoring CT	**NA**	**Yes**	**Yes**	**NA**
Ability to generate a report related to the calcium scoring data.	**NA**	**No**	**Yes**	**NA**
Quantitatively evaluate the wall motion and wall thickening of the heart using longitudinal, radial, and circumferential strain measurements.	**NA**	**Yes**	**NA**	**Yes**
Quantitative strain analysis of the RV	**NA**	**No**	**NA**	**Yes**

Regional strain (by wall and by 17-segment polar maps)	**NA**	**Yes**	**NA**	**Yes**
Comparison to a normal limit (with color-coding) for global and 17-segment regional analysis	**NA**	**Yes**	**NA**	**No**

8. Performance Validation

Emory-CACS: The CACS module was validated against the FDA approved Siemens SyngoVia™ toolbox (K201034). A clinical comparison test was the method used for validation. The test data was comprised a group of 52 patients using 110 vessels with calcified plaques that had been previously scored by Emory radiologists; the same lesions selected by the radiologist were analyzed by the Emory-CACS and SYngo.CT CaScoring modules. Regression analysis was performed between the SyngoVia™ and the Emory-CACS module. On a per patient basis, linear plaque volume regression (m = 1.10; b = 0.46) produced an r2 = 0.99 and Agatston score regression (m = 1.01; b = 1.06) produced an r2 > 0.99. The values obtained by the Emory-CACS module demonstrated excellent correlations with the Syngo.CT CaScoring developed by Siemens Medical Solutions.

ECTb™ Strain: MPI measurements were validated for resting global longitudinal strain vs. an accepted reference standard, TTE echo A clinical comparison test was the method used for validation. Longitudinal, radial, and circumferential strains from a low-risk cohort (n=22) were used to establish normal limits to evaluate against the results of a high-risk cohort (n=80). Positive strain, lower limits of normal were determined as the mean radial strain minus 2-standard deviations (SD). For circumferential and longitudinal strains, both negative in sign, lower limits of normal were determined as the mean strain plus 2-SDs. Validation of strain analysis for ECTb™ 4.3 was performed in 80 patients with variable coronary artery disease (CAD) and 22 patients with low-risk of CAD. In the CAD cohort, longitudinal strain assessed with PET MPI and TTE were strongly correlated at stress (r= 0.68, p <.001) and rest (r= 0.58, p<.001). PET MPI radial strain was also highly correlated with TTE at stress (r=-0.70, p<.001) and at rest (r=-0.59, p<.001). Similarly, PET MPI circumferential strain was highly correlated with TTE at stress (r=0.67, p<.001) and at rest (r=0.69, p<.001). The results demonstrate that all values between ECTb™ Strain and TTE correlated strongly and were found to be highly reproducible.

9: Conclusion

The current device has the same indication for use and has the same technological characteristics as the predicate device(s). The performance of the additional new features have been tested and the results have met the predefined acceptance criteria, and it has been determined to be substantially equivalent to predicate device(s).