6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Cedars-Sinai Medical Center, Department of Medicine, Artificial Intelligence in Medicine Program
DATE PREPARED:	31 October 2012
CONTACT PERSON:	Geoff Pollard, Program Manager 8700 Beverly Blvd Los Angeles, CA 90048 Phone: 310.423.4663
TRADE NAME:	Cedars-Sinai Cardiac Suite Nuclear Medicine Software
CLASSIFICATION NAME:	Emission Computed Tomography System
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER	892.1200
PRODUCT CODE	KPS
PREDICATE DEVICES:	CSMC Cardiac Suite- Nuclear Medicine Software (K112474)

Substantially Equivalent To:
The CSMC Cardiac Suite v2013- Nuclear Medicine Software is substantially equivalent in intended use, principal of operation and technological characteristics to the previously cleared CSMC Cardiac Suite v2012- Nuclear Medicine Software (K112474).

Description of the Device Subject to Premarket Notification:

The Cedars-Sinai Cardiac Suite is a stand-alone software solution for Cardiac SPECT and PET imaging processing and review. Cedars-Sinai Cardiac Suite (non-viewer) minimum system requirements include a computer with at least 1GB RAM, 50MB hard disk space for software installation, a display resolution of at least 1024x768 with 16-bit color, a network adapter, a mouse (or other pointer device; trackpad, trackball, etc...) and one of the following operating systems: Windows XP, Windows Vista, Windows 7, Windows 8, Windows Server 2003, Windows Server 2008, Windows Server 2012, Mac OS X (10.6, 10.7 & 10.8). The viewer component of the Cedars-Sinai Cardiac Suite minimum system requirements is iPad 2, iPad (3rd generation), iPad (4th generation) and iPad Mini. The Cedars-Sinai Cardiac Suite operates on camera independent reconstructed SPECT and/or PET image files. CSMC Cardiac Suite will be marketed as a comprehensive application suite that includes QPS+QGS (Quantitative Perfusion SPECT + Quantitative Gated

SPECT) and CSImport applications. This allows automatic processing and review of quantitative and qualitative information generated by nuclear medicine studies. Purchasable Options consist of Quantitative Blood Pool SPECT (QBS), QARG (for reporting purposes), Fusion (SPECT/CT/CTA and/or PET/CT/CTA), Motion Correction (MOCO), Automated Reconstruction (AutoRECON), Remote Viewer (Viewer) and QPET. QPET also includes viability quantification and two additional databases (rubidium and ammonia) for processing PET studies.

Indication for Use:

The Cedars-Sinai Cardiac Suite of applications is intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. Cedars-Sinai Cardiac Suite may be used in multiple settings including the hospital, clinic, doctors office, or remotely. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

Technological Characteristics:

The modified CSMC Cardiac Suite- Nuclear Medicine Software has the same technological characteristics and is similar in data display and analysis compared to the predicates. The table below illustrates the similarities and differences in Technological Characteristics between the devices.

	Modified CSMC Cardiac Suite	**CSMC Cardiac Suite (K117474)**
Use		
Patient population	Patients who are undergoing Nuclear Medicine Cardiology SPECT or PET procedure	SAME
User	Radiologists, cardiologists, or general nuclear medicine physicians	SAME
Use environment	Multiple settings including the hospital, clinic, doctors office, or remotely	SAME
Features		
Quantitative Gated SPECT	Yes	SAME
Quantitative Perfusion SPECT	Yes	SAME
Quantitative Blood Pool SPECT	Yes	SAME
Quantitative PET	Yes	SAME
Correction of motion artifact	Yes	SAME
Reconstruction Package	Yes	SAME

Performance

Support of the substantial equivalence of the CSMC Cardiac Suite was provided as a

result of software validation, which confirms all features of the device were compliant with the software requirements.

Basis for Determination of Substantial Equivalence:

Upon reviewing and comparing intended use, design, principle of operation and overall technological characteristics, the CSMC Cardiac Suite is determined by Cedars-Sinai Medical Center to be substantially equivalent to existing legally marketed device.

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

July 22, 2014

Cedars-Sinai Medical Center
Department of Medicine
Artificial Intelligence in Medicine Program
% Mr. Geoff Pollard
Program Manager
8700 Beverly Blvd.
LOS ANGELES CA 90048

Re: K141652
CSMC Cardiac Suite Nuclear Medicine Software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: June 17, 2014
Received: June 20, 2014

Dear Mr. Pollard:

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,

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): K141652

Device Name: Cedars-Sinai Medical Center (CSMC) Cardiac Suite v2015- Nuclear Medicine Software

Indications for Use:

The Cedars-Sinai Cardiac Suite of applications is intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. Cedars-Sinai Cardiac Suite may be used in multiple settings including the hospital, clinic, doctors office, or remotely. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 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* Diagnostic and Radiological Health

510(k) k141652