CereMetrix Corp
John Kelley
President
991 Southpark Drive , Suite 200
Littleton, Colorado 80120

February 28, 2018

Re: K173145
Trade/Device Name: CereMetrix Silver
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 26, 2018
Received: February 27, 2018

Dear John Kelley:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173145/S003

Device Name
CereMetrix Silver

Indications for Use *(Describe)*
The CereMetrix Silver software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The brain image modalities include SPECT, PET, MRI and CT as supported by ACR/NEMA DICOM 3.0. CereMetrix Silver assists in the following indications:

- Receive, transmit, store, retrieve, display, print, and process brain images and DICOM objects derived from radiological diagnostic systems, and processing workstations, among others.
- Create, display and print reports from medical images.
- Registration and review of brain images for diagnosis, treatment evaluation, and treatment planning.
- Localization and definition of objects and the differentiation between hyper or hypo perfused tissue, as compared to a composite average, in medical images.
- Creation of clusters for applications including quantitative analysis and archiving clusters for patient follow-up and management.
- CereMetrix Silver is capable of processing and displaying the brain image data in traditional formats, as well as pseudo three-dimensional renderings.
- CereMetrix Silver provides manual and automatic report creation plus the ability to view these reports remotely.
- CereMetrix Silver allows for quantitative and statistical analysis of SPECT brain scans by comparing to a composite average.

When used for diagnostic purposes, the mobile web client is not intended to replace a full workstation and should only be used when there is no access to a workstation.

The software is not to be used for computer aided diagnostic purposes, including mammography CAD.

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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