Cardiovascular Imaging Technologies
% Ms. Melanie Hasek
Associate Director, Regulatory Publishing
PRA Health Sciences
9755 Ridge Drive
LENEXA KS 66219

January 12, 2018

Re: K173547
Trade/Device Name: ImagenUniversal™
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, LLZ
Dated: November 10, 2017
Received: November 16, 2017

Dear Ms. Hasek:

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,

For

Robert 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)*
K173547

Device Name
ImagenUniversal™

Indications for Use *(Describe)*

The ImagenUniversaJTM system is a software. application that allows the user to visualize raw PET and/or PET/CT data, to correct for transmission and emission misregislration, and to correct PET 3D data for photon scatter and prompt gamma photons. The resulting corrected tomograms can be exported to cardiac interpretive software for interpretation. The use of this system is limited to qualified, licensed healthcare providers (radiologists, nuclear cardiologists or nuclear med icine physicians) trained in the use of nuclear medicine imaging devices.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92.

General Information:

A. Submitted By: Cardiovascular Imaging Technologies
4320 Wornall Road, Suite 114
Kansas City, MO 64111
Tel: 816-531-2842
Fax: 816-531-0643

Contact Person: James A. Case

Date Prepared: November 13, 2017

B. Device Trade Name: ImagenUniversal™

Classification Name: System, Emission Computed Tomography
21 CFR 892.1200 (KPS)
System, Image Processing, Radiological
21 CFR 892.2050 (LLZ)

C. Predicate Devices: Siemens Biograph 64 and 40 (K060631)
Siemens Biograph mCT (K151486)
ImagenPRO (K050366)

D. Device Description:

ImagenUniversal™ is a Windows application which allows physicians and healthcare professionals to correct myocardial perfusion PET images for transmission and emission misregistration, prompt gamma events, photon scatter and image noise. The system processes perfusion and gated PET reconstructed emission and transmission data to create corrected 3D tomographic data. The user can select correction parameters, filter settings, range of reconstruction, and registration setting. The use of this system is limited to qualified, licensed healthcare providers (radiologists, nuclear cardiologists or nuclear medicine physicians) trained in the use of nuclear medicine imaging devices.

E. Indications for Use:

The ImagenUniversal™ system is a software application that allows the user to visualize raw PET and/or PET/CT data, to correct for transmission and emission misregistration, and to correct PET 3D data for photon scatter and prompt gamma photons. The resulting corrected tomograms can be exported to cardiac interpretive

software for interpretation. The use of this system is limited to qualified, licensed healthcare providers (radiologists, nuclear cardiologists or nuclear medicine physicians) trained in the use of nuclear medicine imaging devices.

F. Comparison of Technical Characteristics to Predicate Device:

The ImagenUniversal™ system and its predicates, the Biograph™ systems, and the ImagenPRO™ utilize the same type of data sets for analysis and calculation of data.

H. Summary:

Testing and comparison of technological characteristics and intended uses found that all components of the ImagenUniversal™ system are equivalent to the predicates.