MiEGmbH
% Mr. Thomas Kuehl
CEO
Hauptstrasse 112
Seth, Schleswig-Holstein 23845
GERMANY

August 27, 2020

Re: K201807
Trade/Device Name: ANCORIS
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: June 25, 2020
Received: July 1, 2020

Dear Mr. Kuehl:

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or post-marketing 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201807

Device Name

ANCORIS

Indications for Use *(Describe)*

The 'ANCORIS' PET Scanner is designed to acquire data, process and display images by appropriated trained medical professionals via measuring the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body.

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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Submitter Identification

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Date summary prepared: 24th August 2020

Registration Number: 3005128583

Product Identification

Name: ANCORIS

Common Name: Positron Emission Tomography (PET) Scanner

Classification Name: Emission Computed Tomography System
21 C.F.R. § 892.1200

Classification: Class II

Identification of Legally Market and Equivalent Devices

510(k) #	Device	Manufacturer
K130269	ECAT Scintron PET	MiE GmbH
K002584	ECAT ACCEL PET Scanner	CTI PET Systems, Inc.
K013504	ECAT LSO PET/CT Scanner	CTI PET Systems, Inc.

Device Description

The proposed device 'ANCORIS' is a PET system providing volume measurements of metabolic and physiologic processes. It is the same as the legally market device, name 'ECAT ACCEL PET scanner', K002584, from CTI PET Systems (now Siemens Medical), combined with the legally market device, name 'ECAT Scintron PET', K130269 from MiE GmbH.

It is designed to close the economical gap between the demand and availability of stand-alone PET scanner.

The 'ANCORIS' PET Scanner is designed to perform acquisitions, image reconstruction, processing, viewing and analysis of data. It uses the same technology and has the same performance as well as indications for use as the legally market devices.

The system includes the gantry with transmission scan capability, the currently market integrated workstation 'ECAT Scintron PET' (K130269) and the new designed PHS. The system is available as a three detector-ring system with a 16.2cm field of view same as used in currently marketed device ECAT ACCEL PET Scanner (K002584).

Indications for Use

The 'ANCORIS' PET Scanner is designed to acquire data, process and display images by appropriated trained medical professionals via measuring the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body.

Comparison with Predicate Devices

The 'ANCORIS' PET Scanner is similar in measuring design and function to the legally market device 'ECAT ACCEL PET scanner', K002584, as well as the PET Scanner used in the legally market device, name 'ECAT LSO PET/CT Scanner', K013504. Same as in the 'ECAT ACCEL PET scanner' rotating source are used to perform the transmission scan. The main difference of the current device 'ANCORIS' is a PHS (patient handling system) for higher patient weight.

The 'ANCORIS' PET Scanner will use the same computer hard- and software technology as used in the legally market device, name 'ECAT Scintron PET', K130269.

New changes in the current device

- The patient handling system (PHS) is designed for higher patient weights up to 227kg (500lbs). The mechanical technologies are similar to the legally market device 'ECAT ACCEL PET Scanner', K002584. The PHS pallet is designed for higher patient weights and similar attenuation properties.
- The trigger unit for ECG and respiratory gating is integrated into the rear of the ANCORIS PHS and moves together with the pallet. The operation is done via the user touch interface at the gantry.
- The graphical user touch interface displays more information of the acquisition and system status including operation of the trigger unit. The touch interface allows a modern usage of the system.

Performance verification and validation of the device

The performance of the ANCORIS is successful checked by verification and validation of the ANCORIS system. Furthermore, it is checked if the system meets the specifications and fulfills its intended purpose.
The higher patient load of the PHS and the general requirements for basic safety and essential performance is checked during the IEC 60601-1 tests.
The transmission technology by Ge68 rod sources is similar to transmission technology of the legally market device 'ECAT ACCEL PET Scanner', K002584. This is checked by a comparison of the rod source holder, septa, parking positions, attenuation of PHS pallet and the attenuation correction procedure.

Conclusion

The 'ANCORIS' PET System has similar intended use, operating principle and fundamental technologies as legally market devices. The manufacturing, design and development processes of the 'ANCORIS' PET System are conform to currently valid standards including applicable medical device safety and performance.

All test results are, in opinion of MiE GmbH, that the 'ANCORIS' PET System substantially equivalent to the predicated devices.