



Food and Drug Administration
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Silver Spring, MD 20993-0002

General Equipment for Medical Imaging (Oncovision-Gem Imaging S.A.) July 28, 2016
% Mr. Jose Montes
Quality and Regulatory Affairs Manager
Eduardo Primo Yúfera, n° 3
Valencia, 46012
SPAIN

Re: K161631
Trade/Device Name: MAMMI
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: July 20, 2016
Received: July 25, 2016

Dear Mr. Montes:

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,



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

Indications for Use

510(k) Number (if known)

K161631

Device Name

MAMMI

Indications for Use (Describe)

MAMMI (Models FP-0202 and FP-0203) is intended to obtain Positron Emission Tomography (PET) images of breast to detect abnormal metabolic activities, when the patient was injected with FDA approved PET agent. MAMMI should not be used for breast cancer screening.

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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Special 510 (K)
GENERAL EQUIPMENT FOR MEDICAL IMAGING S.A.
MAMMI
510(k) Summary



510(k) number: K161631

Owner's name: General Equipment for Medical Imaging, S. A.
Address: Eduardo Primo Yúfera, 3, 46012, Valencia (Spain)
Phone: + 34 96 372 24 72
Fax number: +34 96 355 65 32
Name of contact person: Jose Montes, Quality and Regulatory Affairs Manager
Date: 04/25/2016

Name of the device: MAMMI
System trade name: MAMMI
Common name: MAMMI Breast PET
Regulatory Class: II
Product Code: KPS
Classification name: Emission computed tomography system

A. LEGALLY MARKETED PREDICATED DEVICES

Product: MAMMI
Manufacturer: General Equipment for Medical Imaging, S. A. (Oncovision-GEM Imaging S.A.)
510(k) number: K140996
Substantial Equivalence Date: 11/06/2014

B. DEVICE DESCRIPTION

MAMMI is a high spatial resolution, small field-of-view breast PET dedicated (PEM) imaging system, specifically developed for close-range, spot, i.e. limited field, imaging. MAMMI is a ring PET scanner, equipped with lutetium-containing gamma-ray detectors (LYSO), which collects gamma rays emitted by injected positron-emitting radiopharmaceuticals, and generates images corresponding to concentration of these radiopharmaceuticals in the body. MAMMI is designed to collect gamma rays from a patient's body part with high efficiency and resolution. In order to achieve this high efficiency, the detectors are positioned around and must cover the body part under examination.

C. INDICATIONS FOR USE

MAMMI (Models FP-0202 and FP-0203) is intended to obtain Positron Emission Tomography (PET) images of breast to detect abnormal metabolic activities, when the patient was injected with FDA approved PET agent. MAMMI should not be used for breast cancer screening.

D. TECHNOLOGY COMPARISON

The technology has not changed. This consists of lutetium-containing gamma-ray detectors (LYSO) that collect gamma rays emitted by injected positron-emitting

radiopharmaceuticals, and generates images corresponding to concentration of these radiopharmaceuticals in the body.

Change of the software version from 2.0 to 2.2

- An improvement in the reconstruction algorithm with PSF correction: it improves the image quality for reconstructed images used for the quality control validation;
- Multilanguage support: all texts have been translated to several languages
- DICOM support: two new software modules to work with the DICOM world: WorkList Tool, used to retrieve worklists from a DICOM Modality Worklist server in order to avoid the manual introduction of patient data and PACSTool, which is used to submit reconstructed images to a DICOM PACS server;
- Automatic deletion of personal health information feature, which is responsible to remove personal data from the system when it is no longer required or when it must be removed due to HIPAA rules.

There have been no hardware changes.

E. BIOCOMPATIBILITY

No new testing was performed as no hardware changes were made from the predicate device

F. ELECTRICAL SAFETY TESTING

No new testing was performed as no hardware changes were made from the predicate device

G. ELECTROMAGNETIC COMPATIBILITY TESTING

No new testing was performed as no hardware changes were made from the predicate device

H. PERFORMANCE TESTING

No new testing was performed as no hardware changes were made from the predicate device

I. SOFTWARE TESTING

Change of the software version from 2.0 to 2.2

Software for MAMMI was designed and developed according to a robust software development process, and was rigorously verified and validated, according to IEC 62304 Medical Device Software - Software Life Cycle Processes and the Guidance For The Content Of Premarket Submissions For Software Contained In Medical Devices - Guidance For Industry And FDA Staff, as was done with the previous version.



Test results indicated that MAMMI complies with its predetermined specification.

Software verification and validation testing has been conducted and documentation provided is consistent with a “moderate” level of concern.

J. CLINICAL IMAGES

No new clinical images have been included. The clinical images included in “Mammi e-book” (Annex 1 of Section 20 of the Submission K140996) are still up to date.

K. CONCLUSION

Based upon a comparison of devices and performance testing results, MAMMI is substantially equivalent to the predicate device.