September 1, 2023

Convergent Imaging Solutions
Mathew Thomas
President
36 Rideau River Lane
Ottawa, Ontario K1S 0X1
Canada

Re: K231047
Trade/Device Name: UniSyn Molecular Imaging (6-3-1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, IYX
Dated: August 2, 2023
Received: August 2, 2023

Dear Mathew Thomas:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231047

Device Name

UniSyn Molecular Imaging (6-3-1)

Indications for Use *(Describe)*

UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT, MR and other medical scanners. It is to be used by qualified radiology and nuclear medicine professionals. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image.

For use with internally administered radioactive products. UniSyn can estimate radiation dose from internalized radioactivity in the human body as a result of a diagnostic or therapeutic medical procedure involving radioactive materials. UniSyn should not be used to deviate from approved product dosing and administration instructions. Refer to the product's prescribing information for instructions.

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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510(k) #: K231047

510(k) Summary

Prepared on: 2023-09-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Convergent Imaging Solutions
Applicant Address	36 Rideau River Lane Ottawa ON K1S 0X1 Canada
Applicant Contact Telephone	1-613-212-0063
Applicant Contact	Mr. Mathew Thomas
Applicant Contact Email	mathew.thomas@convergentimaging.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	UniSyn Molecular Imaging (6-3-1)
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K081987	UNISYN	LLZ
K033960	(Reference Device) OLINDA/EXM v1.0	IYX
K212587	(Reference Device) 3D-RD-S	IYX
K163687	(Reference Device) OLINDA/EXM V2.0	IYX

Device Description Summary

21 CFR 807.92(a)(4)

UniSyn Molecular Imaging (MI) is a Software as a Medical Device (SaMD) that supports the visualization, manipulation and analysis of medical image data acquired or used in radiology and nuclear medicine centers. UniSyn MI is only intended to be used by qualified radiology and nuclear medicine professionals. UniSyn MI is composed of two user-interface components: a patient study browser and the UniSyn MI viewer. The software is available in both thick and thin installations and can be integrated to launch from PACS software.

Using UniSyn MI users can coregister anatomical and molecular images and visualize them in fused and/or standalone display, e.g. single or multi-modal combinations of PET, SPECT, CT, and MR images. Users can also visualize and process planar nuclear medicine (NM) images acquired as single of multi-frame images. The layout of the images shown in the UniSyn MI viewer is highly customisable, a typical layout for a PET/CT study would include single or fused displays of the PET and CT series in multiplanar reformatted (MPR) views as well as a 3D maximum-intensity (MIP) projection rendering of the PET series.

UniSyn MI provides tools to zoom, pan, stack, and window-level the displayed series. Our triangulation tool can be used to localize a single anatomical point of interest among all MPR and MIP views of the series. Region-of-interest (ROI) tools are available to delineate 2D and 3D regions and then compute image statistics within those regions, e.g. ROI area/volumes, minimum, maximum, mean and standard deviation of image pixel values. Various image segmentation tools are included with UniSyn MI to facilitate ROI delineation based on

image pixel data.

UniSyn MI includes a tool for absorbed dose estimation associated with internally deposited radionuclides associated with diagnostic and therapeutic medical procedures. Absorbed dose estimates are based on single- or multi-time point activity measurements of molecular images and absorbed dose coefficients (S-Values) that are based on computational human models.

Once a user has completed their review or analysis of a given study, UniSyn MI provides tools to generate reports and export exemplary image data to share with referring physicians to substantiate their findings.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT, MR and other medical scanners. It is to be used by qualified radiology and nuclear medicine professionals. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image.

For use with internally administered radioactive products. UniSyn can estimate radiation dose from internalized radioactivity in the human body as a result of a diagnostic or therapeutic medical procedure involving radioactive materials. UniSyn should not be used to deviate from approved product dosing and administration instructions. Refer to the product's prescribing information for instructions.

Indications for Use Comparison 21 CFR 807.92(a)(5)

This device has the same intended use as the predicate device (K081987) and the intended use of the reference device K163687 OLINDA/ EXM V2.0.

Technological Comparison 21 CFR 807.92(a)(6)

In all aspects except dosimetry, UniSyn Molecular Imaging has the same technological characteristics and functionality as the predicate device K081987. In the dosimetry aspect, UniSyn Molecular Imaging has the same technological characteristics of the reference device (OLINDA/EXM v2.0, K163687) as they both support whole organ / tissue absorbed dose estimates due to the administration of radiopharmaceuticals using S-Value calculations.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing was not required for functionality that is shared with the predicate (K081987). This functionality was verified and validated using existing verification and validation testing protocols.

Performance testing was completed to validate the technological characteristics of the dosimetry model used in UniSyn MI. Various radionuclides including Fluorine-18, Gallium-68, Iodine-131, Lutetium-177, Technitium-99m, and Yttrium-90 were evaluated. For all tests, dose estimates were compared to reference values described below. Relative differences (reported as percentages) were used to characterize agreement. The acceptance criteria was set as a relative difference at or below 10%.

Validation of normal organ dosimetry was based on comparisons to values from published data. Data evaluated for both male and female patients demonstrated high overall agreement with published data demonstrating relative differences (mean relative differences < 2%) below the acceptance criteria.

Validation of tumor dosimetry was based on comparisons to the sphere model of OLINDA/EXM v1.0 (K033960). These comparisons included tumor sizes ranging from 3.9 to 600 cc. The overall agreement across all tumor sizes was excellent with mean relative differences that ranged from <1% up to 6.5%, depending on the radionuclide.

The performance data exhibit high concordance with data found in published literature and generated by FDA-cleared devices and met the acceptance criteria. We have demonstrated that the dosimetry model implemented in UniSyn MI has been validated, and the performance data provided demonstrate that UniSyn Molecular Imaging (6-3-1) performs comparably to the predicate device that is currently marketed for the same intended use.