April 13, 2023

Inter Medical Medizintechnik GmbH
% Hans-Guenter Osiek
Managing Director
Daimlerstrasse 34-36
Luebbecke, D-32312
Germany

Re: K230393
Trade/Device Name: UniCam Evo Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 14, 2023
Received: February 14, 2023

Dear Hans-Guenter Osiek:

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
Magnetic Resonance and Nuclear Medicine Team
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.

510(k) Number *(if known)*
k230393

Device Name
UniCam Evo Software

Indications for Use *(Describe)*
The UniCam Evo Software package is indicated for nuclear medicine image post-processing software for scintigraphic and SPECT imaging. UniCam Evo is indicated for processing and quantification of planar and tomographic bone scintigraphy scans, processing of cerebrovascular scintigraphic scans, processing of planar and tomographic cardiovascular scintigraphic studies, renal dynamic scans, planar and SPECT lung scintigraphy, planar gastrointestinal scintigraphic scans, liver scintigraphy, thyroid, parathyroid scintigraphy and displaying multimodal image fusion between SPECT/CT/MR/PET/ultrasound modalities.

The UniCam Evo Software is intended for nuclear medicine specialists, nuclear medicine radiologists, or trained medicine technologists. The operator shall have basic computer operation skills.

The software loads scintigraphic data sets in Dicom format from the local database or queries the corresponding dicom data from a PACS archive. The operator may perform analysis on the data, ROI analysis, tomographic reconstruction, organ dependent procedure steps and the software displays the results in form of images, numerical data or curves. The operator may print the results, store as an image or dicom secondary capture. Reconstructed transversal, coronal and sagittal slices can be also stored in Dicom 3.0 format.

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) Summary

510(k) Submitter's Name:
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Establishment Registration Number:

Date Prepared: 17 July 2022

Device Name:
Trade name: UniCam Evo Software
Common Name: Evo Software
Regulatory Class: II

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Classification Name:	21CFR 892.2050, Medical image management and processing system
Panel:	Radiology Devices
Product Code:	LLZ

Identification of Predicate Device(s):

Manufacturer	Device name	510(k) Number
PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. 595 MINER RD.	ODYSSEY LX, MODEL 211320	K003437
CONVERGENT IMAGING SOLUTIONS 49 FIRST AVE. SUITE B OTTAWA, ONTARIO, CA K1S 2G1	UniSyn Image Fusion	K081987

Device Description:

UniCam Evo is a software package for processing planar, whole body, dynamic planar and SPECT nuclear medicine data sets. The UniCam Evo Software is used for digital images capture, pre-processing, saving, post-processing, multiplanar reconstruction, multimodal image fusion, multimodal image registration, 3D rendering, viewing, printing, archiving and transferring between image viewing workstations. The UniCam Evo Software is intended for nuclear medicine specialists, nuclear medicine radiologists, or trained medicine technologists. The operator shall have basic computer operation skills.

The software loads scintigraphic data sets in Dicom 3.0 format from the local database or queries the corresponding dicom data from a PACS archive. The operator may perform analysis on the data, ROI analysis, tomographic reconstruction, organ dependent procedure steps and the software displays the results in form of images, numerical data or curves. The operator may print the results, store as an image or dicom secondary capture. Reconstructed transversal, coronal and sagittal slices can be also stored in Dicom format.
The data to be processed can be transferred via the DICOM 3.0 Standard to another Nuclear Medicine Workstations of another Manufacturer or from a Gamma Camera / SPECT acquisition workstation.
The software runs under standard Windows operating systems, such as XP, 7, 8, 10, 11. The basic operation principle of the processing program is displayed as flowchart below:

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Intended Use Statement:

The UniCam Evo Software package is indicated for nuclear medicine image post-processing software for scintigraphic and SPECT imaging. UniCam Evo is indicated for processing and quantification of planar and tomographic bone scintigraphy scans, processing of cerebrovascular scintigraphic scans, processing of planar and tomographic cardiovascular scintigraphic studies, renal dynamic scans, planar and SPECT lung scintigraphy, planar gastrointestinal scintigraphic scans, liver scintigraphy, thyroid, parathyroid scintigraphy and displaying multimodal image fusion between SPECT/CT/MR/PET/ultrasound modalities.

The UniCam Evo Software is intended for nuclear medicine specialists, nuclear medicine radiologists, or trained medicine technologists. The operator shall have basic computer operation skills.

The software loads scintigraphic data sets in Dicom format from the local database or queries the corresponding dicom data from a PACS archive. The operator may perform analysis on the data, ROI analysis, tomographic reconstruction, organ dependent procedure steps and the software displays the results in form of images, numerical data or curves. The operator may print the results, store as an image or dicom secondary capture. Reconstructed transversal, coronal and sagittal slices can be also stored in Dicom 3.0 format.

Predicate Device Comparison

The primary legally marketed device is the ODYSSEY LX, MODEL 211320 (K003437) and the second predicate device is the UniSyn Image Fusion (K081987) Software. The intended use of the device and the predicate devices are similar and the device under subject combines features from both predicate devices. The combined features are quantitative analysis of nuclear medicine data processing, reporting, displaying images, storing images in Dicom format, ROI analysis from predicate device 1, and multimodal image fusion, multimodal image registration, displaying, storing images in Dicom format from predicate device 2.

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Device Comparison Chart:

Description	Subject device	Primary Predicate device	Predicate device 2	Significant difference
Device name and 510k number	UniCam Evo Software	ODYSSEY LX, MODEL 211320 (K003437)	UniSyn Image Fusion (K081987)	
Intended use/Indications for use	The UniCam Evo Software package is indicated for nuclear medicine image post-processing software for scintigraphic and SPECT imaging. UniCam Evo is indicated for processing and quantification of planar and tomographic bone scintigraphy scans, processing of cerebrovascular scintigraphic scans, processing of planar and tomographic cardiovascular scintigraphic studies, renal dynamic scans, planar and SPECT lung scintigraphy, planar gastrointestinal scintigraphic scans, liver scintigraphy, thyroid, parathyroid scintigraphy and displaying multimodal image fusion between SPECT/CT/MR/PET/ultrasound modalities. The UniCam Evo Software is intended for nuclear medicine specialists, nuclear medicine radiologists, or trained medicine technologists. The operator shall have basic computer operation skills.	The Philips Medical Systems ODYSSEY LX computer workstation performs acquisition, processing, display, archiving, printing and networking of Nuclear Medicine data.	UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT and MR 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.	Similar

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	The software loads scintigraphic data sets in Dicom format from the local database or queries the corresponding dicom data from a PACS archive. The operator may perform analysis on the data, ROI analysis, tomographic reconstruction, organ dependent procedure steps and the software displays the results in form of images, numerical data or curves. The operator may print the results, store as an image or dicom secondary capture. Reconstructed transversal, coronal and sagittal slices can be also stored in Dicom 3.0 format.			
Device				
Where to use	Office settings in clinic or hospital	Office settings in clinic or hospital	Office settings in clinic or hospital	No significant difference
Stand-alone Software	yes	yes	yes	No significant difference
Web application	no	no	no	No significant difference
Mobile medical app	no	no	no	No significant difference
Operating system	Windows 7 64 bit or later	Linux	Microsoft Windows XP and later	Odyssey LX and UniSyn operate on different operating system, for further details see *Explanation A)* below
User interface	Graphical User Interface	Graphical User Interface	Graphical User Interface	No significant difference
Nuclear Medicine data quantification algorithms according to the	yes	yes	yes	No significant difference

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SNMMI and EANM Procedure Standards and Guidelines				
ROI drawing, reporting, 3D rendering, Multiplanar reconstruction, Study comparison	yes	yes	yes	No significant difference
Planar Nuclear Medicine Scintigraphy Processing features				
Thyroid uptake, Parathyroid suppression, Bone two and three phase, Brain scintigraphy, Renal scintigraphy, Lung planar, Multiple gated cardiac blood pool imaging, First-pass radionuclide ventriculography, HIDA, Gallbladder ejection fraction calculation, Gastric emptying, Sentinel node, Esophageal transit, Salivary Gland	yes	yes	Not specified	*Primary Predicate device:* No significant difference *Predicate device 2* is not intended for the full spectrum of scintigraphic image processing.
SPECT processing features				
Lung, bone, brain perfusion, myocardial perfusion	yes	yes	Not specified	*Primary Predicate device:* No significant difference *Predicate device 2* is not intended for the full spectrum of

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				scintigraphic image processing.
Multimodal image fusion				
Image fusion / overlay display, Opacity control, Image registration	yes	Not specified	yes	*Primary Predicate device:* is not intended for multimodal image fusion. *Predicate device 2:* No significant difference

Explanation A) The technological characteristics between the UniCam Evo Software and Odyssey LX are different, as the software operates on different operating system. Although Odyssey LX runs under a different operating system with another graphical user interface, both devices are image-processing programs, the different operating systems, do not limit the functionality of the software.

The Unicam Evo Software and the predicate devices are software product that run on PC-based workstations. Image data is input to the devices and used to generate 2D and 3D views, perform image processing, quantitative processing, image fusion and co-registration. Like the two predicate devices, the software has image processing, quantitative analysis, Region Of Interest drawing and image registration abilities, fusion of images from different-modalities, image storage and retrieval, as well as patient information management functions. The UniCam Evo and UniSyn Image Fusion are software products that accept multiple image data types including magnetic resonance, computed tomography, single photon emission computed tomography, or positron emission tomography. Odyssey LX accepts only nuclear medicine, namely, planar and SPECT scintigraphic data sets. The UniCam Evo Software and the predicate devices are capable to display, load, process and store image data in Dicom format.

Nonclinical testing summary

Verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics as the predicate devices. The testing results support that the functional testing met for the acceptance of the device. The UniCam Evo Software passed all testing and supports the claims of substantial equivalence to the predicate devices.

The software has been extensively tested using verification and validation test protocols. An emphasis on early testing improves the quality and reliability of software prior to release.

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by comparing - for the selected test studies - the results from the current version with the results from reference values wherever possible the phantom studies are generated and the results from the program are validated with the expected values calculated in an independent way. The results of processing are validated (for a carefully selected series of studies) against the values from the published original reference.

The carried out tests are finally being evaluated and released in an all-embracing risk analysis. The results of the software tests are part of the evaluation of the remaining risks (see Device hazard analysis).

During a review it was checked, if all specifications were implemented in the software as descript in the specification and matches to the requirements.

Each system integration / validation tests contain the following information: the test description, name of the tester, its signature, date of the test, software version number, steps required to perform the test, pass fail criteria for the test step and a checkbox for documenting the passes/failed step.

Summary of the performed tests:

All performed tests passed and have met the acceptable test criteria. There were no test failures.

Summary conclusion:

The device has been designed, verified and validated complying with applicable safety standards for this type of medical equipment. Bench and clinical data demonstrate that processing methods, images and results are equivalent comparing to the predicate devices. No adverse effect has been detected.
Before placing the system on the market and use on human beings, Inter Medical has reviewed all known information and carried out a risk analysis for the software. The comparison table between UniCam Evo Software to predicate devices showed the close similarities and therefore we concluded that it is substantially equivalent to the legally marketed device.