Medsynaptic Private Ltd.
℅ Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

November 22, 2019

Re: K192508
Trade/Device Name: MEDSYNAPSE RIS PACS & MEDSYNAPSE VNA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 19, 2019
Received: November 20, 2019

Dear Mr. Kamm:

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,

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)*
K192508

Device Name
MEDSYNAPSE RIS PACS & MEDSYNAPSE VNA

Indications for Use *(Describe)*
Medsynapse RIS PACS Software is intended for use as a fully web based application on an off-the shelf PC which is networked with a Medsynapse RIS PACS server. The Medsynapse RIS PACS software can process medical images from DICOM compliant modalities and non DICOM sources. The Medsynapse RIS PACS software provides toolsets for performing measurements on DICOM images, importing and presenting data from modalities (DICOM and non-DICOM), solving clinical calculations, and creating and distributing structured reports.

It enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, cardiologists, technologists, sonographers, technicians, nurses and clinicians. MIP, MPR, and Fusion are not intended for Mammography use.

Medsynapse VNA is an open standards based archiving methodology used for storing images in non-proprietary format.

The Medsynapse RIS PACS Software may be used to process DICOM MG “For Processing” images and also for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography.

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 K192508

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Telefax +91-20-25650412
URL: http://www.medsynaptic.com
Contact: Dr Ashish Dhawad, Chief Executive Officer
Date prepared: November 18, 2019

1. **Trade Name: MEDSYNAPSE RIS PACS & MEDSYNAPSE VNA**
   Common Name: PACS Software
   Classification Name: System, image processing, radiological
   Regulation Description: Picture archiving and communications system
   Product code LLZ,
   Regulation: 892.2050
   Class of device: Class II.

2. **The legally marketed device to which we are claiming equivalence:**
   K190232, Synapse PACS, FUJIFILM Corporation
   Common Name: PACS Software
   Classification Name: System, image processing, radiological
   Regulation Description: Picture archiving and communications system
   Product code LLZ,
   Regulation: 892.2050
   Class of device: Class II.

3. **Reference device: K093247, Medsynaptic Private Ltd**
   Trade Name: Medsynapse PACS Software
   Common Name: PACS Software
   Classification Name: System, image processing, radiological
   Regulation Description: Picture archiving and communications system
   Product code LLZ,
   Regulation: 892.2050
   Class of device: Class II.

4. **Description of device:** Medsynapse RIS (Radiology Information System) PACS is a fully web based, enterprise-wide application intended for communication, storage, display, printing, and processing of medical images. Its software components perform operations related to image manipulation and measurements relevant to radiology and cardiology. As a software-only device, it does not control image acquisition. Typical users of Medsynapse RIS PACS are radiologists, cardiologists, technologists, sonographers, technicians, nurses, and clinicians. The software runs on standard PC equipment using MS Windows operating systems meeting minimum system requirements. Medsynapse VNA (Vendor Neutral Archive) is an open standards-based archiving methodology

used for storing images in non-proprietary format**.**

5. **Indications for use:** Medsynapse RIS PACS Software is intended for use as a fully web based application on an off-the shelf PC which is networked with a Medsynapse RIS PACS server. The Medsynapse RIS PACS software can process medical images from DICOM compliant modalities and non DICOM sources. The Medsynapse RIS PACS software provides toolsets for performing measurements on DICOM images, importing and presenting data from modalities (DICOM and non-DICOM), solving clinical calculations, and creating and distributing structured reports.

   It enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, cardiologists, technologists, sonographers, technicians, nurses and clinicians. MIP, MPR, and Fusion are not intended for Mammography use.
   Medsynapse VNA is an open standards based archiving methodology used for storing images in non-proprietary format.
   The Medsynapse RIS PACS Software may be used to process DICOM MG "For Processing" images and also for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography.. (Rx Only)

6. **Technological characteristics:** Comparison Table

Characteristic	**K190232, Fujifilm Synapse PACS.**	**MEDSYNAPSE RIS PACS & MEDSYNAPSE VNA**	**Technological Comparison**
Indications	FUJIFILM Synapse PACS Software is intended for use as a web based application on an off-the shelf PC which meets or exceeds minimum specifications and is networked with a FUJIFILM Synapse PACS server. The FUJIFILM Synapse PACS Software can process medical images from DICOM compliant modalities and non-DICOM sources. The FUJIFILM Synapse PACS Software provides toolsets for performing measurements on DICOM images, importing and presenting data from modalities (DICOM and non-DICOM), solving clinical calculations, and creating and distributing structured reports. The FUJIFILM Synapse PACS Software is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. It enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, cardiologists, technologists, sonographers, technicians, nurses and clinicians. MIP, MPR, and Fusion are not intended for mammography use. The FUJIFILM Synapse PACS Software may be used to process FUJIFILM's DICOM MG "For Processing"	Medsynapse RIS PACS Software is intended for use as a fully web based application on an off-the shelf PC which is networked with a Medsynapse RIS PACS server. The Medsynapse RIS PACS software can process medical images from DICOM compliant modalities and non DICOM sources. The Medsynapse RIS PACS software provides toolsets for performing measurements on DICOM images, importing and presenting data from modalities (DICOM and non-DICOM), solving clinical calculations, and creating and distributing structured reports. It enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, cardiologists, technologists, sonographers, technicians, nurses and clinicians. MIP, MPR, and Fusion are not intended for Mammography use. Medsynapse VNA is an open standards based archiving methodology used for storing images in non-proprietary format. The Medsynapse RIS PACS Software may be used to process DICOM MG "For Processing" images and also for the display, manipulation, and interpretation of lossless	The indications mean the same thing with slightly different wording.

Characteristic	K190232, Fujifilm Synapse PACS.	MEDSYNAPSE RIS PACS & MEDSYNAPSE VNA	Technological Comparison
	images and also for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography.	compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography	
Features	DICOM compatible	DICOM compatible	SAME
	Multipurpose, enterprise-wide application intended for communication, storage, display, printing, and processing of medical images	SAME	SAME
	Typical users of Synapse PACs are radiologists, cardiologists, technologists, sonographers, technicians, nurses, and clinicians	SAME	SAME
Modalities	Plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from DICOM compliant modalities. Mammography with appropriate display resolution	SAME	SAME
HIPAA Compliance	YES	SAME	SAME
Computer/ Operating System	Windows PC	SAME	SAME

7. **Bench/Performance Testing:** The results of bench testing (software validation and risk analysis for a moderate level of concern device) shows that this new device poses no new issues of safety or effectiveness, has essentially the same technological characteristics as the predicate, and is therefore substantially equivalent to the predicate device. Software and labeling was developed in accordance with the following FDA guidance documents*: Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices; Guidance for Industry Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff.*
Risk management was conducted in accordance with IEC 14971, Application of Risk Management to Medical Devices.

8. **Clinical Testing: Not required for a showing of substantial equivalence.**

9. **Conclusion:** Based on comparison to the 510(k) summary of the predicate device, its technical characteristics, the indications for use, and the near identical characteristics of the two products, we conclude that the MEDSYNAPSE RIS PACS & MEDSYNAPSE VNA is substantially equivalent to the named predicate device.