DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 2, 2016

Medsynaptic Private Ltd.
% Daniel Kamm. P.E.
Submission Correspondent
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K163158
Trade/Device Name: Medsynapse Zero Footprint Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 7, 2016
Received: November 10, 2016

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. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163158

Device Name
MEDSYNAPSE ZERO FOOTPRINT VIEWER

Indications for Use *(Describe)*
With appropriate display monitors, lighting, image quality, and level of lossy image compression the use of MEDSYNAPSE ZERO FOOTPRINT VIEWER is to distribute medical images & associated documents on desktop (Windows & Linux) & mobile platform (Android, iOS, Blackberry, Windows) using browsers like Internet Explorer, Mozilla Firefox, Safari, UC Browser or Google Chrome within or out of hospital. The users of the systems will be trained healthcare professionals. This software is not appropriate for primary diagnosis of Mammograms.

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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 K16 .

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URL: http://www.medsynaptic.com
Contact: Dr Ashish Dhawad, Chief Executive Officer
Date prepared: November 7, 2016

1. **Trade Name: MEDSYNAPSE ZERO FOOTPRINT VIEWER**
   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: RapidResults, K141881, RamSoft, Inc.**
   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. **Description of device: MEDSYNAPSE ZERO FOOTPRINT VIEWER allows distribution of images within and outside the Hospital. It acquires, transmits, stores, retrieves, and displays digital images and related patient information from a variety of imaging sources and communicates the information over a network. It facilitates image viewing at diagnostic, reporting, consultation, and remote computer workstations, as well as archiving of pictures on magnetic or optical media using short- or long-term storage devices. MEDSYNAPSE ZERO FOOTPRINT VIEWER allows communication using local or wide-area networks, public communications services, systems that include modality interfaces, and gateways to healthcare facility and departmental information systems.**

4. **Indications for use: With appropriate display monitors, lighting, image quality, and level of lossy image compression the use of MEDSYNAPSE ZERO FOOTPRINT VIEWER is to distribute medical images & associated documents on desktop (Windows & Linux) & mobile platform (Android, iOS, Blackberry, Windows) using browsers like Internet Explorer, Mozilla Firefox, Safari, UC Browser or Google Chrome within or out of hospital. The users of the systems will be trained healthcare professionals. This software is not appropriate for primary diagnosis of Mammograms. (Rx Only)**

5. **Technological characteristics: Comparison Table**

Characteristic	RapidResults, K141881, RamSoft, Inc.	MEDSYNAPSE ZERO FOOTPRINT VIEWER	Technological Comparison
Indications	This software displays medical images and associated documents. With appropriate display monitors, lighting, image quality, and level of lossy image compression, the software is intended for use as a primary diagnostic (on desktop platform) and non-diagnostic review tool (on mobile platform) for use by trained healthcare professionals. Each healthcare professional must determine if the level of loss is acceptable for their purpose. This software is not suitable for primary diagnosis of mammograms.	With appropriate display monitors, lighting, image quality, and level of lossy image compression the use of MEDSYNAPSE ZERO FOOTPRINT VIEWER is to distribute medical images & associated documents on desktop (Windows & Linux) & mobile platform (Android, iOS, Blackberry, Windows) using browsers like Internet Explorer, Mozilla Firefox, Safari, UC Browser or Google Chrome within or out of hospital. The users of the systems will be trained healthcare professionals. This software is not appropriate for primary diagnosis of Mammograms	The indications mean the same thing with slightly different wording.
Features	Zero-download Image Viewer	SAME	SAME
	Devices: Windows, Android, MAC, iPhone, iPad	SAME	SAME
	Touch or Keyboard and Mouse	SAME	SAME
	Multiple browser support	SAME	SAME
	Diagnostic use on desktops but not mobile devices.	SAME	SAME
	Window/Level, Zoom, Rotation, Flip, Pan, Measure, and Annotation. Does not produce or alter any images and medical data.	SAME	SAME
Modalities	View all image modalities, including Xray, CT, MRI, color ultrasound and XRay angiography.	SAME	SAME
HIPAA Compliance	The Viewer secured connects to the PACS using HTTPS. Images stay in the PACS, not on the device. When the web browser or mobile application is closed, all images and information are gone from the device. It does not store images on any user's device.	SAME	SAME
Architecture	Server-based software solution that display images and reports from a PACS using a zero-footprint application (HTML5), no installation needed.	SAME	SAME

Characteristic	RapidResults, K141881, RamSoft, Inc.	MEDSYNAPSE ZERO FOOTPRINT VIEWER	Technological Comparison
Technology	Use of various technology standards (LDAP, SSO, HTTPS, HTML, HTML5, CSS, XML, web services, etc.)	SAME	SAME

6. 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.

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

8. 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 Zero Footprint Viewer is substantially equivalent to the named predicate device.