K093247

510(K) Summary K09

DEC - 2 2009

Medsynaptic Private Ltd
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URL: http://www.medsynaptic.com
Contact: Dr Ashish Dhawad
Chief Executive Officer
Date prepared: July 23, 2009

1. Trade Name: Medsynapse PACS Software

2. Common Name: PACS Software

3. Classification Name: system, image processing, radiological

4. Regulation Description Picture archiving and communications system, product code LLZ, Regulation: 892.2050 Class of device: Class II.

5. The legally marketed device to which we are claiming equivalence Voyager PACS System, Voyager Imaging, K062062.

6. Description of device: Medsynapse is a web PACS, which allows distribution of images within and outside the Hospital using networking technology. It does not require installation of any software and can be operated directly from the browser providing ease of use from anywhere.

7. Indications for use: Medsynapse PACS Software is a WEB software based device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices. secondary capture devices, scanners. imaging gateways, etc.). Images and data can he captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor that offers at least 5 Megapixel resolution and meets other technical specifications reviewed and accepted by FDA.

8. Technological characteristics: The software is installed on a web connected PACS server with the following minimum requirements:
A) Minimal Hardware Requirement
1. Intel Xeon Quad core Processor 3.0 GHz
2. Intel Server Mother Board
3. 4 GB Fully Buffered ECC RAM
4. 1 TB HDD
5. 1GbPS LAN Port

B) Minimal Software Requirement
1. Windows Server 2003 Standard Edition
2. SQL server 2005 Standard Edition

The client computer requires web access using Internet Explorer with the following minimum configuration:
- **Pentium IV core 2 duo processor @ 2.8 GHz or faster**
- **1 GB of RAM or more**
- **High speed video graphic card which will support at least 1024x 768 of resolution in 32 bit color**
- **High resolution monitor with at least 1024 x 768 resolution support in 32 bit color**
- **MS Windows 2000, XP, 2003,Vista with MS Internet Explorer 6 or higher**

Macintosh and other operating systems and internet browsers are not supported at this time

Internet connection: High speed (Broadband) internet connection with at least 512 KbPS of speed, such as wireless, DSL, Cable internet

9. Performance: The results of bench testing (software validation and risk analysis) shows that this new device poses no new issues of safety or effectiveness, and is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Medsynaptic Private Ltd.
% Mr. Daniel Kamm, P.E.
Principal Consultant
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8726 Ferrara Ct.
NAPLES FL 34114

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Re: K093247
Trade/Device Name: Medsynapse PACS Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 7, 2009
Received: October 15, 2009

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093247

Device Name: Medsynapse PACS Software

Indications For Use:
Medsynapse PACS Software is a web software based device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices. secondary capture devices, scanners. imaging gateways, etc.).

Images and data can he captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor that offers at least 5 Megapixel resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K093247