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

March 29, 2016

Synaptive Medical Inc.
% Mr. Cameron Piron
President
MaRS Centre, South Tower, 101 College Street, Suite 200
TORONTO, ON M5G 1L7
Canada

Re: K153284
Trade/Device Name: Synaptive ImageDrive Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 1, 2016
Received: February 3, 2016

Dear Mr. Piron:

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)*
K153284

Device Name
Synaptive ImageDrive Pro

Indications for Use *(Describe)*
Synaptive ImageDrive Pro is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations.
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA.
Typical users of this system are trained professionals, including but not limited to radiologists, physicians, nurses, medical technicians, and assistants.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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510(K) Summary

Table 5.1 510(k) Summary (As required by section 21 CFR 807.92(c))	
Submitter:	Synaptive Medical Inc. MaRS Centre, South Tower 101 College Street, Suite 200 Toronto, ON M5G 1L7 Canada
Contact Person:	Cameron Piron President Telephone: 416-673-6679 Email: cameron.piron@synaptivemedical.com Synaptive Medical Inc. MaRS Centre, South Tower 101 College Street, Suite 200 Toronto, ON M5G 1L7 Canada
Date Prepared:	November 10, 2015
Trade Name:	Synaptive ImageDrive Pro
Common/Usual Name:	PACS
Classification:	21 CFR 892.2050 System, Image Processing, Radiological
Product Code:	LLZ
Manufacturer:	Synaptive Medical Inc. MaRS Centre, South Tower 101 College Street, Suite 200 Toronto, ON M5G 1L7 Canada
Establishment Registration:	3010439744
Predicate Device:	**Manufacturer:** GE Healthcare **Trade name:** Centricity PACS-IW with Universal Viewer **510(k) Number:** K123174 **Date Cleared:** November 16, 2012
Device Description	Synaptive ImageDrive Pro is a medical imaging informatics system that allows the storage, management, display and analysis of imaging and non-imaging data. The Synaptive ImageDrive Pro

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	data repository can be populated either by manually uploading data through the user interface (UI) or in an unattended fashion by automatically receiving DICOM objects or HL7 messages from other information systems such as PACS and EMRs. Automatic data processing rules can be configured to process data when it arrives in the system. An example of this is when pre-operative MR scans are done and sent to ImageDrive to ensure that they were acquired using appropriate scan protocol before they are consumed downstream by other Synaptive applications, such as BrightMatter Plan (cleared as a Class-II device, K140337). Once in the system, the data is indexed so that it can be easily searched in the future. Imaging data can also be de-identified and securely shared with authorized persons. Further, the system provides an extensible architecture to enable local or distributed processing of the data. As data accumulates in the system, analytics can be generated to summarize, for example, intra- and inter-patient statistics and trends in surgical treatment planning based on surgical plan data that is output from external software that can generate data in compatible formats. An example of such external system is the surgical planning software manufactured by this applicant - - BrightMatter Plan. The subject device is composed of the following key features: • A hierarchical folder system • Three data storage areas • Data processing functionality • Analytics capability • Image viewing capability
Indications for Use	Synaptive ImageDrive Pro is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations.

Table 5.1 510(k) Summary (As required by section 21 CFR 807.92(c))	
	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA. Typical users of this system are trained professionals, including but not limited to radiologists, physicians, nurses, medical technicians, and assistants.
Summary of Technological Comparisons	Design comparison: Both the subject device and the predicate are internet based software-only medical devices that allow storage, management, display and analysis of imaging and non-imaging data. Both systems support communication of data to and from the system using DICOM and HL7 data communication standards. Both systems are capable of communicating with EMR and PACS. Technology comparison: Both systems are designed to be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations and utilize commercial computer hardware platforms and operating systems. Neither of the systems produce any original medical images and receive medical images and information various data sources. The information can be stored, communicated, processed and displayed across computer networks at distributed locations.
Non-Clinical Testing	Following testing was conducted on Synaptive ImageDrive Pro device: • Software verification testing for each requirement specification. • System validation testing using intended users. The following quality assurance measures were applied during development of the software system: • Software development life cycle • Software risk assessment • Risk assessment of OTS software • Risk assessment from Cyber and Information security perspective

Table 5.1 510(k) Summary (As required by section 21 CFR 807.92(c))	
	• Software configuration management and version control • Software issue tracking and resolution.
Design Validation	Design validation was performed using Synaptive ImageDrive Pro in simulated use settings by intended users. The results support substantial equivalence to the predicate device and demonstrate that Synaptive ImageDrive Pro is safe for its intended use.
Clinical Testing	This technology is not new, therefore a clinical study was not considered necessary prior to release. Additionally, the substantial equivalence of the device is supported by the non-clinical testing.
Conclusion:	Synaptive ImageDrive Pro system is a medical system that allows the storage, management, display and analysis of imaging and non-imaging data. It has been shown in this 510(k) submission that the differences between the subject device and the predicate device do not raise any new questions regarding safety and effectiveness. Synaptive ImageDrive Pro as designed and manufactured, is substantially equivalent to, and as safe and effective as, the referenced predicate device.