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

PSP Corporation
% Ms. Adrienne Lenz
Senior Consultant, QA and RA
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816 Congress Avenue, Suite 1400
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March 24, 2016

Re: K152716
Trade/Device Name: EV Insite System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 1, 2016
Received: March 3, 2016

Dear Ms. Lenz:

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,

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)*
K152716

Device Name
EV Insite System

Indications for Use *(Describe)*
EV Insite System by PSP Corporation is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks. Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants. Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.

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

# EV Insite System

# K152716

1. **Submission Sponsor**

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3. **Date Prepared**

March 1, 2016

4. **Device Identification**

Trade/Proprietary Name: EV Insite System

Common/Usual Name: Picture archiving and communications system (PACS)

Classification Name: Picture archiving and communications system

Regulation Number: 892.2050

Product Code: LLZ, System, Image Processing, Radiological

Device Class: Class II

Classification Panel: Radiology

**5. Legally Marketed Predicate Device(s)**

K123174 Centricity PACS-IW with Universal Viewer, manufactured by GE Healthcare

**6. Device Description**

The EV Insite System is comprised of two pieces of software: EV Insite R and EXtServer. It is a medical image display and processing software product that provides users with capabilities relating to the storage, communication, digital processing and display within the system or across computer networks of medical images. Images can be searched and displayed in a number of layouts as well as stacked. Image and information processing functions include: paging, magnification, demagnification, gradation, annotation, PET/CT fusion, multiplaner reconstruction (MPR), Maximum Intensity Projection (MIP), superimposing, measurement, multi-display, flip, rotate, and mirror, cine window level adjustment, and comparison display.

The EV Insite system includes features to access and manage medical imaging studies from DICOM 3.0 compliant imaging modalities, and provides information after processing for diagnosis. The EV Insite System software displays image processing results and allows online image search and reading. It does not perform any automatic diagnosis.

The system does not produce any original medical images but can be used for primary diagnosis, except for lossy compressed mammographic images which must not be reviewed for primary image interpretations unless using an FDA cleared display. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA. All images located on the EV Insite system have been received from DICOM compliant modalities and/or image acquisition systems.

The EV Insite system allows trained professionals to display and manipulate images stored in DICOM archive devices. These trained professionals include but are not limited to physicians, radiologists, nurses, medical technicians, and assistants.

The EV Insite system is designed to be deployed over conventional networking infrastructure available in most healthcare organizations and utilizes commercially available computer platforms and operating systems.

## 7. Indication for Use Statement

EV Insite system by PSP Corporation is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants. Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.

## 8. Substantial Equivalence Discussion

The following table compares the EV Insite System to the predicate device with respect to indications for use, principles of operation, and technological characteristics. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

**Table 5A – Comparison of Characteristics**

| **Manufacturer** | **PSP Corporation** | **GE Healthcare** | **Significant Differences** |
|---|---|---|---|
| **Trade Name** | **EV Insite System** | **Centricity PACS-IW** | |
| **510(k) Number** | This submission | K123174 | None |
| **Product Code** | LLZ | LLZ | None |
| **Regulation Number** | 892.2050 | 892.2050 | None |
| **Indications for Use** | EV Insite system by PSP Corporation is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks.<br>Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants. Lossy compressed | Centricity PACS-IW with Universal Viewer 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 | None |

| Manufacturer | PSP Corporation | GE Healthcare | Significant Differences |
|---|---|---|---|
| **Trade Name** | **EV Insite System** | **Centricity PACS-IW** | |
| **Indications for Use, continued** | mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA. | primary image interpretations. Mammographic images<br>may only be interpreted using an FDA approved<br>monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA.<br>Typical users of this system are trained professionals, including but not limited to radiologists, physicians,<br>nurses, medical technicians, and assistants. | |
| **Mechanism of Action** | Software that runs on commercially available off-the-shelf computer hardware platforms. | Software that runs on commercially available off-the-shelf computer hardware platforms. | None |
| **Technology Overview** | Medical image display and interpretation software product that is part of a picture archiving and communications system. It provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital mammograms). The software is run on commercially available hardware specified in the labeling. | Medical image display and interpretation software product that is part of a picture archiving and communications system. It provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital mammograms). The software is run on commercially available hardware specified in the labeling. | None |

| Manufacturer | PSP Corporation | GE Healthcare | Significant Differences |
|---|---|---|---|
| **Trade Name** | **EV Insite System** | **Centricity PACS-IW** | |
| **Compatible Imaging Modalities** | Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Nuclear medicine (NM), Computerized radiography (CR), Digital mammography (MG), Digital x-ray (DX), Positron Emission Tomography (PET/PT), X-Ray Angiography (XA), Digital Intra-oral X-Ray (IO), Radiotluoroscopic X-ray (RF), Secondary Capture Images (SC), Visible Light (VL) Endoscopic, Microscopic and Photographic ImageStorage and other DICOM imaging modalities. | Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Nuclear medicine (NM), Computerized radiography (CR), Digital mammography (MG), Digital x-ray (DX), Positron Emission Tomography (PET/PT), X-Ray Angiography (XA),Digital Intra-oral X-Ray (IO), Radiotluoroscopic X-ray (RF), Secondary Capture Images (SC), Visible Light (VL) Endoscopic, Microscopic and Photographic Image Storage, Slide Coordinates Microscopic Image Storage, Presentation States (PS), Key image Notes (KIN) and other DICOM imaging modalities. | EV Insite System has fewer compatible imaging modalities. Both systems are compatible with the most widely used imaging modalities. |
| **Image Sources** | DICOM, JPEG Baseline (Process 1), JPEG Extended (Process 2 & 4), JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1]), RLE Lossless | DICOM, JPEG and JPEG 2000 | EV Insite System does not support Jpeg2000. |
| **Image and Information Processing Functions** | Image Search/list<br>Image Display (number of layouts)<br>Image stack<br>Paging,<br>Magnification<br>Demagnification, | Image Search/list<br>Image Display (number of layouts)<br>Image stack<br>Mammography Viewer<br>Paging,<br>Slab Scroll<br>Magnification | Centricity has more processing functions, including special processing for mammograms, 3-D Rendering, Ultrasound Measurements, Spine Labeling, |

| Manufacturer | PSP Corporation | GE Healthcare | Significant Differences |
|---|---|---|---|
| **Trade Name** | **EV Insite System** | **Centricity PACS-IW** | |
| **Image and Information Processing Functions continued** | Windowing (Window level adjustment),<br>Annotation,<br>PET-MR/CT Fusion,<br>Multiplaner reconstruction (MPR),<br>Maximum Intensity Projection (MIP),<br>Image overlay,<br>Measurement,<br>Multi-display,<br>Flip, Rotate, and Mirror<br>Cine<br>Comparison display<br>Convolution. | Demagnification,<br>Sharpen<br>Annotation,<br>Image overlay,<br>PET/CT Fusion<br>Multiplaner reconstruction (MPR),<br>Maximum Intensity Projection (MIP),<br>3-D Rendering<br>Measurement,<br>Multi-display,<br>Flip, Rotate, and Mirror<br>Cine<br>Window level adjustment, and<br>Comparison display<br>Ultrasound Measurements<br>Spine Labeling<br>Ortho tools<br>Vessel Analysis<br>Advanced PET/CT<br>Digital subtraction angiography | ortho images, vessel analysis, advanced PET/CT and digital subtraction angiography. EV Insite System's fusion function includes PET/MR in addition to PET/CT like Centricity. |

**9. Non-Clinical Performance Data**

As part of demonstrating safety and effectiveness of EV Insite System and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, PSP Corporation completed non-clinical performance tests. The EV Insite System meets all the requirements for overall design results confirming that the design output meets the design inputs and specifications for the device.

The EV Insite System passed all the testing in accordance with internal requirements shown below to support substantial equivalence of the subject device:

- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a malfunction or a latent design flaw in the software device could lead to an erroneous diagnosis that would lead to a minor injury. Verification

and validation of the EV Insite System Software consists of unit testing, software testing and system verification and validation.

- The EV Insite System software was developed and tested following processes in compliance with IEC 62304: 2006 Medical Device Software - Software Life Cycle.

## 10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

## 11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The EV Insite System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).