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

DR Systems, Inc.
% Ms. Kimberly J. Meade
Manager, Regulatory Affairs/Quality Assurance
10140 Mesa Rim Road
SAN DIEGO CA 92121

March 10, 2015

Re: K143318
Trade/Device Name: DR Systems Zero Download 3D Viewer (Z3D)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 18, 2015
Received: February 18, 2015

Dear Ms. Meade:

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 A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K143318

Device Name
DR Systems Zero Download 3D Viewer (Z3D)

Indications for Use *(Describe)*

DR Systems Z3D is intended to provide reading physicians, referring physicians, and other appropriate healthcare professionals tools to aid in interpreting medical images, including:

• Displaying DICOM compliant medical image volumes, such as CT, MRI, and PET.

• Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images

• Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path.

• Creating series of DICOM images and individually captured images that can be displayed and stored in a PACS.

• Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms.

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)

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Section 5 – 510(k) Summary

Submitter: DR Systems, Inc.
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Contact: Kimberly J. Meade, MSQA, ASQ CQA
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Phone: (858) 625-3344, x2260
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Date Prepared: November 17, 2014

Trade Name: DR Systems Zero Download 3D Viewer (Z3D)

Common Name: Digital Image Processing

Classification Name: Systems, Image processing, Radiological

Classification Regulation: 21 CFR 892.2050, Class II

Product Code: 90 LLZ

Predicate Device: K060505 - Voxar 3D Product Family

Device Description: DR Systems Z3D (Zero Download 3D) advanced imaging solution supports MIP (maximum intensity project), MPR (multiplanar reconstruction), 3D volume rendering, and cardiac calcium scoring. The system employs server-based rendering and browser-based viewing. Reading physicians, referring physicians, and other appropriate healthcare personnel and can employ advanced image processing and display from local or remote locations.

Viewing Modes:

- Multiplanar reconstruction
- Two 3-D viewing modes, one showing 4 images, and one showing 6 images
- Cardiac calcium scoring

DR Systems Z3D is similar to the predicate device, Voxar 3D. Both are PACS system accessories that allow the user to view and manipulate 3D image data sets. DR Systems Z3D does not have an AvelP analysis tool. The principles of operation and technological characteristics of the new and predicate device are the same.

Technical Specifications

Specifications	
Processor	o Intel® Core™ i5 3 GHz or faster: o Quad-core minimum.
Operating system	▪ Microsoft® Windows® 7/8.1 ▪ Apple® Mac OS ® X v10.6, v10.7, or v10.8
Hard drive	160 GB 7200 RPM minimum
Available hard drive space	20 GB with a minimum free disk space of at least 15%, for program files and to copy exams to the comnputer's local drive
RAM	4 GB (minimum)
Keyboard and mouse	Standard or USB keyboard and a 5-button optical mouse is required.
NIC	Integrated. Ethernet data rate: ▪ Minimum: 100 Mb/s ▪ Recommended: 1 Gb/s
Monitor	17" 1280 x 1024 resolution (minimum) 20" 1600 x 1200 resolution 24" 1920 x 1200 resolution
Network Interface	For connection to the PACS local area network (LAN) 100 Mbit connection recommended
Internet browser	▪ Standard web browser that supports Adobe Flash Player 10 or greater and Silverlight 4 or greater: o Internet Explorer® starting with 8. o Mozilla Firefox® starting with 17 o Google Chrome™ starting with version 32 o Apple Safari® starting with 5.0
Access	▪ Application Gateway Server (AGS) ▪ Web address. For example: http://<AGS>/DRPacs/zda/

Intended Use/ Indications for Use:

DR Systems Z3D is intended to provide reading physicians, referring physicians, and other appropriate healthcare professionals tools to aid in interpreting medical images, including:

- Displaying DICOM compliant medical image volumes, such as CT, MRI, and PET.
- Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images.
- Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path.
- Creating series of DICOM images and individually captured images that can be displayed and stored in a PACS.
- Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms.

Technological Characteristics:

Z3D receives and processes image volumes from cross-sectional DICOM medical imaging examinations such as CT, MRI, and PET. The system provides a graphical user interface to enable healthcare professional to execute the functions supporting the intended use. Image processing is performed on a secure image server, and images are then displayed using a browser-based viewer.

Nonclinical Testing:

DR Systems Z3D was designed, developed and tested according to DR System's written procedures. Testing included verification, validation and evaluation of human factors and usability.

The following quality assurance measures were applied to the development of Z3D:

- Risk analysis
- Requirements reviews
- Design reviews
- Performance testing (verification)
- Simulated use testing (validation and human factors and usability)

Clinical Testing:

N/A

Conclusion: The information in this 510(k) submission demonstrates that based on the nonclinical testing, the subject, Zero Download 3D Viewer is substantially equivalent to the predicate device with respect to safety, effectiveness, and performance.