DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

3DISC Americas
% Mr. Daniel Kamm
Principal Engineer
Kamm and Associates
8870 Ravello Court
NAPLES FL 34114

August 3, 2015

Re: K151687
Trade/Device Name: QuantorView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 16, 2015
Received: June 23, 2015

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,

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)*
K151687

Device Name
QuantorView

Indications for Use *(Describe)*
QuantorView is PACS image viewing software for DICOM images produced by imaging equipment (CR, DR, CT, MRI, Ultrasound and etc). The software allows physicians to provide medical services by accessing image data and patient information from remote locations. It also enables the images to be stored to the local database of your personal computer allowing database management to operate efficiently. Physicians can utilize the software tools for viewing, researching, teaching, teleconferencing and online collaboration.

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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510(k) Summary K15_____

This 510(k) summary information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date prepared: June 16, 2015

1. Company and Correspondent making the submission:
   Name – 3D Imaging & Simulations Corp.
   Address – 815, Tamnip-Dong, Yuseong-Gu, Daejeon, Korea
   Telephone – +82-42-931-2100
   Fax – +82-42-931-2299
   Contact – Jiin Jung / Vice President
   E-mail – jiinjung@3-disc.com

2. Device :

Trade/proprietary name:	QuantorView
Common Name:	PACS Software
Classification Name:	Picture Archiving and Communications System

3. Predicate Device :

Manufacturer:	eFilm.
Device:	eFilm Workstation
510(k) Number:	K012211

4. Classifications Names & Citations :
   21CFR 892.2050, LLZ – Picture Archiving and Communications System, Class 2

5. **Description :** This is a PC software product used for viewing digital medical images having the following features:

DICOM File Support

- Read and display all DICOM files (mono-frame, multi-frame)
- Read and display non-DICOM file
- JPEG Lossy, JPEG Lossless, JPEG2000, RLE
- Read and write DICOM CD/DVD (DICOMDIR support)
- Export DICOM files to BMP, TIFF, JPEG
- Convert Non-DICOM images to DICOM
- Convert multi-frame image to AVI file.

DICOM Network Support

- DICOM Storage SCU/SCP
- DICOM Query/Retrieve SCU/ SCP
- DICOM Print SCU with 8, 12 bit support

Viewer Functions

- Customizable toolbars
- NN, linear, cubic, super sampling interpolation
- ROIs: polygons, circles, rectangles and etc.

- Custom LUT and curve
- CT/MR scout line view
- Thumbnail images support
- Support 1 to 4 monitors
- User defined hanging protocol, tool bar, overlay
- Local database support
- Local backup support

6. Indications for use :

QuantorView is PACS image viewing software for DICOM images produced by imaging equipment (CR, DR, CT, MRI, Ultrasound and etc). The software allows physicians to provide medical services by accessing image data and patient information from remote locations. It also enables the images to be stored to the local database of your personal computer allowing database management to operate efficiently. Physicians can utilize the software tools for viewing, researching, teaching, teleconferencing and online collaboration.

7. Comparison with predicate device :

3D Imaging & Simulations Corp. believes that the QuantorView is substantially equivalent to eFilm Workstation.

	eFilm Workstation eFilm Medical, Inc (Now known as Merge Healthcare) K012211	QuantorView 3D Imaging & Simulations Corp.
Intended Use	eFilm™ Workstation is a software application that is used for viewing medical images. eFilm™ Workstation receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources). Images are stored, communicated, processed and displayed on the local disc of a workstation and/or across computer networks at distributed locations. Tasks that users may perform when viewing images include, but are not limited to: adjustment of window width and level; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips of images. In addition, eFilm™ Workstation can be integrated with an institution's existing HIS or RIS for a fully integrated electronic patient record. Typical users of eFilm™ Workstation are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.	QuantorView is PACS image viewing software for DICOM images produced by imaging equipment (CR, DR, CT, MRI, Ultrasound and etc). The software allows physicians to provide medical services by accessing image data and patient information from remote locations. It also enables the images to be stored to the local database of your personal computer allowing database management to operate efficiently. Physicians can utilize the software tools for viewing, researching, teaching, teleconferencing and online collaboration.
Operational Characteristics	Uses PC computers running Windows XP, Vista, Windows 7.	SAME, Windows 7 or 8

	eFilm Workstation eFilm Medical, Inc (Now known as Merge Healthcare) K012211	QuantorView 3D Imaging & Simulations Corp.
Typical Users	Trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.	SAME
IMAGE MANIPULATION	Rotate, flip, and invert images	SAME
MEASUREMENT	Distance, angle, CTR	SAME
CD/DVD Burning	YES	YES
DICOM Print	YES, regular or DICOM printer	SAME
IMPORT Images	Both DICOM and NON-DICOM (JPEG and TIFF)	SAME
Export Images	Export images as JPEG files Export images as AVI files	SAME, plus BMP and TIFF
Backup	YES	YES, auto and manual
Medical Device Security – MDS	Not specified	Disclosure Statement Executed
Connection	Ethernet	SAME
DICOM Compatibility	DICOM 3.0 Compliant	DICOM 3.0 Compliant
DICOM FILE SUPPORT	JPEG Lossy, JPEG Lossless, JPEG2000	JPEG Lossy, JPEG Lossless, JPEG2000, RLE (Run Length Encoding)

Summary of comparison: All technical and functional characteristics of the predicate and the QuantorView product are essentially the same, including the platform and DICOM image compatibility. Therefore the QuantorView software product is substantially equivalent to the legally marketed predicate.

8. Non-clinical performance testing. Software validation and risk analysis was done according to FDA Guidance document: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005. Testing verified compliance with the DICOM 3 standard. A DICOM 3 compliance statement has been executed. Off-the Shelf Software and Device Security issues were addressed and documented. A Manufacturer Disclosure Statement for Medical Device Security – MDS – has been executed.

9. Clinical performance testing: Not applicable or required.

10. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification 3D Imaging & Simulations Corp. concludes that the QuantorView software is safe and effective and substantially equivalent to predicate device as described herein.