DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 23, 2016

4QImaging, LLC Dba Qmetrics Technologies
% Mr. Edward Schreyer
CEO
1250 Pittsford-Victor Road
Suite 110, Bldg. 200
PITTSFORD NY 14534

Re: K161559
Trade/Device Name: Kuvia3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 2, 2016
Received: June 6, 2016

Dear Mr. Schreyer:

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,

Michael D. O'Hara 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)*
K161559

Device Name
Kuvia3D

Indications for Use *(Describe)*
Kuvia3D software is intended for the display and analysis of DICOM image data to facilitate 3D visualization of joint anatomy for planning surgical and non-surgical therapies.

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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Summary of Safety and Effectiveness

Device Name: Kuvia3D

Date Prepared: May 24, 2016

Submitter: Qmetrics Technologies
1250 Pittsford-Victor Rd.
Suite 110, Bldg. 200
Pittsford, NY 14534

Contact: Edward Schreyer
Edward.schreyer@qmetricstech.com
Phone: +1 585 301-4300 x141
Fax: +1 585 270-4686

Device Classification:

Trade Name	Kuvia3D®
Common Name	Picture Archiving and Communications System (PACS)
Device Classification Name	System, Image Processing, Radiological
Device Class	Class II
Regulation	892.2050
Product Code	LLZ
Classification Panel	Radiology

Predicate/Reference Devices:

	Predicate Device	Reference Device	Reference Device
Trade Name	3D-DOCTOR	ClearCanvas RIS/PACS	RTVue XR
Device Class	Class II	Class II	Class II
Common Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Optical Coherence Tomography (OCT)
510(k) Submitter/Holder	Able Software 5 Appletree Lane	ClearCanvas, Inc. 439 University	Optovue, Inc. 45531 Northport

	Lexington, MA 02420-2406	Ave., Suite 1920 Toronto, ON M5G 1Y8	Loop West Fremont, CA 94538
510(k) Number	K003746	K110332	K120238
Regulation Number	21 CFR 892.2050	892.2050	21 CFR 886.1570
Product Code	90 LLZ	90 LLZ	HLI
Classification Panel	Radiology	Radiology	Opthalmic

Intended Use:
Kuvia3D software is intended for the display and analysis of DICOM image data to facilitate 3D visualization of joint anatomy for planning surgical and non-surgical therapies.

Kuvia3D is indicated for Prescription Use only.

Device Description:
Kuvia3D is a software system used to display, analyze and generate three-dimensional visualizations of DICOM image data. The software is supported on an off-the-shelf personal computer system platform running the Microsoft Windows operating system. The user will transfer medical image data to the Kuvia3D system from a DICOM image system (such as a PACS) and proceed to use Kuvia3D's viewing and segmentation tools to segment the image data as desired. Once the user has completed segmenting the image data, they can convert the segmented region to a 3D rendered surface and adjust the view of the segmented anatomy as desired. Linear measurements may be taken in the 2D image as well as the 3D surface rendering. Screen captures of the 3D surface rendering window may be saved as derivative images and appended to the imaging study, or transferred to other DICOM image systems.

Major Functions performed by Kuvia3D:

- Exchange of medical image data in DICOM standard format between the Kuvia3D system and DICOM-compatible imaging systems, such as MRI or CT scanners or PACS systems.
- Storage of image data
- Exchange of DICOM image data with other Kuvia3D systems
- Multi-planar image display, including 3D rendering display
- Segmentation of image data, including editing of object boundaries.

- Analysis of image data, including linear length.
- 3D display of adult articular knee cartilage as segmented, color-coded by thickness.

Technical Characteristics:

Kuvia3D is a stand-alone software package used on general-purpose hardware meeting the minimum requirements specified in the labeling/documentation. It is based upon standard Microsoft™ technology. Use of Kuvia3D does not involve patient contact, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, reviews images, generates/corrects segmentations as necessary and reviews information generated by Kuvia3D. The intended use and general technological characteristics of Kuvia3D are the same as those of the predicate device; a reference device has been included to demonstrate that certain technical characteristics absent from the predicate but present in Kuvia3D are common with a more recently cleared device in the product code LLZ.

The following table illustrates the comparison of specific features and functionality of Kuvia3D to the predicate devices, demonstrating substantial equivalence.

Feature	**Kuvia3D (Subject Device)**	**3D-Doctor (Predicate Device)**	**ClearCanvas (Reference Device)**	**RTVue XR (Reference Device)**
Intended Use				
Storage and exchange of DICOM medical images	Yes	No	Yes	No
Display and analysis of images	Yes	Yes	Yes	Yes
3D rendering and display of images	Yes	Yes	No	Yes
Specific Functionality				
Query/import/send/receive image data per DICOM file transfer standards	Yes	No	Yes	No
Store image data locally	Yes	Yes	Yes	Yes

Feature	Kuvia3D (Subject Device)	3D-Doctor (Predicate Device)	ClearCanvas (Reference Device)	RTVue XR (Reference Device)
Features to search, display and select image data based on DICOM header tag information	Yes	No	Yes	No
Display 2D image data, including multi-planar views	Yes	Yes	Yes	No
Display 3D image data	Yes	Yes	No	Yes
Adjust display of image data, including zoom/scale, window/level.	Yes	Yes	Yes	Yes
Segment selected regions of interest	Yes	Yes	No	No
Analyze/measure images	Yes	Yes	Yes	Yes
Convert segmented regions to a 3D surface-rendered display	Yes	Yes	No	Yes
Manipulate display of 3D objects (rotate, zoom, etc)	Yes	Yes	No	Yes
Color-coded thickness display of anatomy	Yes	No	No	Yes
Design				
Supported on standard, off-the-shelf Windows platform	Yes	Yes	Yes	No
Conforms to DICOM standard for data exchange	Yes	No	Yes	No
Conforms to JPEG standard for lossless compress of digital medical images	Yes	No	Yes	No
System comprised of client and server software components	Yes	No	Yes	No

Color Coding of anatomical thickness measurements:

The color coding of cartilage thickness is equivalent to the color coding and thickness map display of corneal and ganglion cell complex structures provided by the reference device RTVue XR (K120238).

Color coding the thickness of anatomical features has also been demonstrated for more than a decade with results published in the open literature (e.g. for measuring bladder wall thickness and corneal thickness). Color coding merely provides a simplified means of rapidly assessing differences in thickness (as opposed to moving a cursor over parts of interest and reading thickness data displayed on a screen). The basic information on which the coding is based does not change. Digital data displayed and thicknesses rendered via color coding do not raise new questions of safety and effectiveness since the underlying algorithms and libraries used to generate the segmentations are the same for each.

Testing:

Kuvia3D complies with the voluntary DICOM and JPEG standards for device performance and is designed and manufactured according to engineering quality processes and standards as detailed in the 510(k) submission. Verification activities were conducted on system, unit and software component levels to validate that Kuvia3D conforms to defined product and user requirements and intended uses. Nonclinical software testing was conducted under simulated use conditions. Predefined acceptance criteria were met and demonstrate that the device is as safe and effective as the predicate devices.

Substantial Equivalence Conclusion:

Kuvia3D is substantially equivalent to the predicate device as listed in terms of intended use, specific features/functionality, and design. Color-coded display of anatomical feature size is also a feature found in reference device RTVue XR (K120238). The thickness values are presented to the user as a color-coded display, a feature similar to the predicate. This and any other difference between Kuvia3D and the predicate device do not raise any new questions of safety or effectiveness.

Conclusion:

The 510(k) Pre-Market Notification for Kuvia3D contains adequate information and data to determine that Kuvia3D is as safe and effective as the legally marketed predicate device.