CurveBeam, LLC
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
WARREN NJ 07059

August 7, 2018

Re: K181962
Trade/Device Name: CubeVue
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 20, 2018
Received: July 23, 2018

Dear Mr. Yungvirt:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

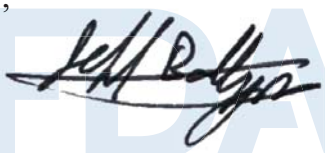
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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)*

K181962

Device Name
CubeVue

Indications for Use *(Describe)*

CubeVue serves as an accessory to Cone Beam CT extremity imaging devices with the intended use to retrieve, display, and distribute 2D and 3D volumetric image data. The image displaying component allows users to manipulate the images to aid in diagnosis and treatment planning, including rotating and navigating through 3D renderings and 2D MPR slices, adjusting display settings, and making measurements.

It is the User's responsibility to ensure monitor quality and ambient light conditions are consistent with the clinical application.

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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Section 5
510(k) Summary

510 (k) Submitter/Owner	CurveBeam, LLC 175 Titus Ave, Suite 300 Warrington, PA 18976 Phone: 267-483-8081 Fax: 267-483-8086
Contact Person	Senior Project Engineer 267-483-8081 Email: Stuti.singh@curvebeam.com
Date Prepared	August 3, 2018
Trade Name	CubeVue
Model Number	SWCV10
Common Name	Picture Archiving Communications System
Classification Name	Picture Archiving Communications System
Product Code	LLZ
510(k) Type	Traditional
Regulation Number	892.2050
Device Classification	Class II

Predicate Device:

Company	Device name	Product Code	510(k)	Regulation Number	Device Classification
Pixmeo Sarl	Osirix MD	LLZ	K101342	892.2050	Class II

This is the first 510(k) submission for this software as a standalone device. Previously, this software had been approved as a component of CurveBeams's pedCAT (510(k) number K113548) and In Reach (510(k) number K170789) Cone Beam Computed Tomography Imaging systems. Upon approval of this application, CurveBeam intends to sell this software independently, instead of packaged with its imaging devices.

Indications for Use:

CubeVue serves as an accessory to Cone Beam CT extremity imaging devices with the intended use to retrieve, display, and distribute 2D and 3D volumetric image data. The image displaying component allows users to manipulate the images to aid in diagnosis and treatment planning, including rotating and navigating through 3D renderings and 2D MPR slices, adjusting display settings, and making measurements.

It is the User's responsibility to ensure monitor quality and ambient light conditions are consistent with the clinical application.

Device Description:

CubeVue serves as an accessory to Cone Beam CT extremity imaging devices with the intended use to retrieve, display, and distribute 2D and 3D volumetric image data.

CubeVue provides a list of patient scans that have been sent to the its image database through its DICOM interface or imported locally by the user. The user can browse, search, and sort the patient list to select a patient and open his or her image data.

The main screen displays a 3D rendering of the image in addition to axial, sagittal, and coronal slices. In the slices, the user can navigate through the volume by paging and rotating. The user can also adjust the window level, zoom, and pan of the 2D slices. In the 3D volume, the user can rotate the volume, cut through a plane, and change the displayed tissue density threshold and rendering style.

The user can make measurements on the image including distances, angles, and density values.

The user can export patient data to a file or media, with the option to anonymize patient demographic information. It supports DICOM and JPEG for image communication.

Substantial Equivalence Summary:

The indications for use for CubeVue are a subset of those for Osirix MD. While Osirix MD is intended to be used for viewing CT, MR, CR, DR, US, and other DICOM compliant data, CubeVue is only intended for viewing extremity Cone Beam CT and extremity X-Ray data. Osirix MD can also be used to review Mammographic images while CubeVue cannot. Although CubeVue's indications for use are a subset of those of Osirix MD's, its capabilities for this subset are substantially equivalent as outlined in the table below. CubeVue's labeling indicates the type of datasets it is intended for viewing and states that it not does not use lossless compression. Therefore, when used as intended, CubeVue functions safely and effectively for its intended purpose.

Performance testing included software validation, verification and testing. CubeVue functioned as intended and the observed results demonstrated substantial equivalence with the predicate device.

Functionality	CurveBeam CubeVue	Osirix MD
Indications for Use	CubeVue serves as an accessory to Cone Beam CT extremity imaging devices with the intended use to retrieve, display, and distribute 2D and 3D volumetric image data. The image displaying component allows users to manipulate the images to aid in diagnosis and treatment planning, including rotating and navigating through 3D renderings and 2D MPR slices, adjusting display settings, and making measurements. It is the User's responsibility to ensure monitor quality and ambient light conditions are consistent with the clinical application.	OsiriX MD" M is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed marnmographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mamnmographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with the clinical application.
The device shall have the ability to view DICOM tags	Yes	Yes
The device shall have the ability to import/export DICOM data to another AE or export media	Yes	Yes
The device shall have the ability to view dose reports	Yes	Yes
The device shall have the ability to export images as JPEG	Yes	Yes
The device shall have the ability to view 2 series, side by side	Yes	Yes
The device shall have the ability to view 3D CT volumes using multi-planar-reformatting (MPR) (axial, sagittal, coronal)	Yes	Yes

The device shall have the ability to view 3D CT volumes in MPR using an arbitrary curve	Yes	Yes
The device shall have the ability to adjust the rotation (X/Y/Z) of 3D CT volumes.	Yes	Yes
The device shall have the ability to cut 3D CT volumes at arbitrary angles	Yes	Yes
The device shall have the ability to adjust Window/Level of 3D CT volumes.	Yes	Yes
The device shall have the ability to adjust the zoom of 3D CT volumes.	Yes	Yes
The device shall have the ability to adjust to adjust the center (move, pan) of 3D CT volumes.	Yes	Yes
The device shall display orientation markers [right(R), left(L), anterior(A), posterior(P), head(H), and feet(F)] on 3D CT volumes.	Yes	Yes
The device shall have the ability to adjust slice thickness on all MPR views.	Yes	Yes
The device shall have the ability to render both maximum-intensity-projection (MIP) or radiographic views.	Yes	Yes
The device shall have the ability to display Hounsfield Unit (HU) measurements with mean, standard deviation, and	Yes	Yes

area/volume on 3D CT volumes.		
The device shall have the ability to measure and display length and angles on 3D CT volumes.	Yes	Yes
The device shall provide surface and volume rendering of the bone, soft tissue and soft tissue with transparency showing the bone	Yes	Yes
The device shall have the following 3D volume render view capabilities crop a 3D volume interactively	Yes	Yes
The device shall have the following 3D volume render view capabilities create STL (Stereo lithography) file format based on desired HU value, with desired name, to be used in third party software.	Yes	Yes
The device shall have the following 3D volume render view capabilities segmentation of bones or user-defined regions	Yes	Yes
HIPPA compliance, hide patient list, hide patient demographics, anonymize patient information	Yes	Yes
The device shall conform to the following consensus standards: DICOM and JPEG.	Yes	Yes
For prescription use	Yes	Yes

Safety and Effectiveness Information:

The CubeVue software is a Class II medical device.

Conformity

The CubeVue device has been tested to the following standards to ensure safety, effectiveness, and compliance with industry norms:

[NEMA] [PS 3.1 – 3.20] [Digital Imaging and Communications in Medicine (DICOM) Set] [2016]

[ISO/IEC] [10918-1] [Information Technology - Digital Compression And Coding Of Continuous-Tone Still Images: Requirements And Guidelines] [02/15/1994]

Testing Results

The software passed all applicable sections of the consensus standards. These results indicate the software will be functional in utilizing JPEG compression, processing DICOM data, and interacting with DICOM entities.

Verification and Validation testing confirmed that the software performed to the system requirements. The results from these test reports indicate that the functionalities equivalent to the predicate device work as intended, verifying that CubeVue is indeed substantially equivalent to Osirix MD.

FDA Guidance

The following FDA Guidance Documents were regarded to the extent they were applicable in the preparation of this 510(k) Submission

- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices

Conclusion:

CurveBeam, LLC has demonstrated through its comparison of characteristics with the predicate device and comparison of performance testing with the predicate device that the CubeVue device is substantially equivalent to the predicate device.