AcroViz, Inc.
% Yung-Chin Hsu
Chief Technology Officer
Rm. 6, 11F, No. 152, Sec. 1
Zhongxiao E. Rd., Zhongzheng Dist.
Taipei, Taiwan 10050
REPUBLIC OF CHINA

September 9, 2020

Re: K201948
Trade/Device Name: AcroDTI Visualizer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 20, 2020
Received: July 13, 2020

Dear Yung-Chin Hsu:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201948

Device Name

AcroDTI Visualizer

Indications for Use *(Describe)*

AcroDTI Visualizer is an image processing software that allows the user to calculate and display DTI from diffusion MRI (dMRI) data. This software is intended to be utilized by trained physicians to visually evaluate the DTI index maps.

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.

510(k) Summary

Date July 3, 2020

Manufacturer AcroViz Inc.
Rm. 6, 11F., No. 152, Sec. 1,
Zhongxiao E. Rd., Zhongzheng Dist.,
Taipei City 10050, Taiwan (R.O.C.)

Contact Person Yung-Chin Hsu
Chief Technology Officer
Rm. 6, 11F., No. 152, Sec. 1,
Zhongxiao E. Rd., Zhongzheng Dist.,
Taipei City 10050, Taiwan (R.O.C.)
Phone: +886-982-963-908
E-mail: eric.ychsu@acroviz.com

Device Trade Name AcroDTI Visualizer

Common Name System, Image Processing, Radiological

Classification Name Picture Archiving and Communications System

Device Class II

Classification Panel Radiology Devices

Product Code LLZ

Regulation Number 892.2050

Device Description and Technology Characteristics AcroDTI Visualizer is a software for processing and viewing Diffusion Tensor Imaging (DTI) from dataset of Diffusion Weighted Imaging (DWI) acquired with Magnetic Resonance Imaging (MRI).

AcroDTI Visualizer calculates and displays DTI maps which reveal diffusion properties of local tissue. The software displays the DTI maps in axial, coronal, and sagittal views, and is able to

adjust the image brightness and contrast to assist visual evaluation.

AcroDTI Visualizer provides support for automated processing of diffusion MRI data in Digital Imaging and COmmunications in Medicine (DICOM) format. The software reads DICOM files in DVD (or CD) exported either from the MR scanner or from a Picture Archiving and Communications System (PACS).

Indications for Use

AcroDTI Visualizer is an image processing software that allows the user to calculate and display DTI from diffusion MRI (dMRI) data. This software is intended to be utilized by trained physicians to visually evaluate the DTI index maps.

Predicate Device(s)

Predicate Device	Predicate Software	Manufacturer	510(K) Number
syngo.MR General; syngo.MR Cardiology; syngo.MR Neurology	Software *syngo.MR VB20*	Siemens Medical Solutions USA, Inc.	K163294
Carestream Vue PACS	Carestream Vue PACS	Carestream Health, Inc.	K170580

Performance Data Non-Clinical Tests

The following performance data were provided in support of the substantial equivalence determination.

The software for this device was considered as a “moderate” level of concern. 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 verification and validation testing results support that all the software specifications have met the acceptance criteria. The human factor engineering file was provided and the human factors validation testing was conducted and showed that the device is safe and effective for the intended users, uses, and use environments.

The performance comparison studies between subject device and legally marketed devices were conducted using qualitative and quantitative methods respectively. Experienced physicians

were recruited to evaluate the performance between subject device and legally marketed devices. The results show that AcroDTI Visualizer has high similarity with the legally marketed devices and support the substantial equivalence.

The following standards/ guidance applies:

- IEC 62304:2006+AMD1:2015, Medical device software - Software life cycle processes, Ed.1.1
- IEC 82304-1:2016, Health software - Part 1: General requirements for product safety
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- ISO 14971:2019, Medical devices - Application of risk management to medical devices
- ASTM D4169-16. Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 62366-1:2015, Medical devices - Part 1: Application of usability engineering to medical devices

Evaluation was completed following above standards and documents. Conformity to these standards demonstrates that the proposed subject device met the standards' established acceptance criteria for the device. This supports substantial equivalence to its predicates.

Substantial Equivalence

The subject device has same indications for use, technology, operation principle and technical characteristics with the predicate device(s). Verification activities were performed on subject device and all tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the device do not affect the indications for use of the device or raise any unsolved issues. There are no significant differences between subject device and the predicate device(s) that would adversely affect the use of the product. We conclude that subject device is substantially equivalent to predicate devices.

Conclusion

In all verification and validation tests, AcroDTI Visualizer meets the pre-specified acceptance criteria that are considered essential for its indications for use and is considered substantially equivalent to the predicate devices.

	Subject Device	Predicate Device	Primary Predicate Device
Device Name	AcroDTI Visualizer	syngo.MR General; syngo.MR Cardiology; syngo.MR Neurology	Carestream Vue PACS
510(k)	K201948	K163294	K170580
Applicant	AcroViz Inc.	Siemens Medical Solutions USA, Inc.	Carestream Health, Inc.
Regulation Number	892.2050	892.2050	892.2050
Product code	LLZ	LLZ/ LNH	LLZ
Classification	II	II	II
Prescription or OTC use	Prescription	Prescription	Prescription
Indications for Use	**AcroDTI Visualizer is an image processing software that allows the user to calculate and display DTI from diffusion MRI (dMRI) data. This software is intended to be utilized by trained physicians to visually evaluate the DTI index maps.**	The software comprising the syngo.MR post-processing applications is post-processing software/applications to be used for viewing and evaluating the designated images provided by a magnetic resonance diagnostic device. All of the software applications comprising the syngo. MR post-processing applications have their own indications for use.	The Carestream Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems. The system is to be used by trained professionals including, but

		syngo.MR General is a syngo based post-processing software for viewing, manipulating and evaluating MR images. syngo.MR Cardiology is a syngo based post-processing software for viewing, manipulating and evaluating MR cardiac images. **syngo.MR Neurology is a syngo based post-processing software for viewing, manipulating, and evaluating MR neurological images.**	not limited to, physicians and medical technicians. The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians. The system contains a Perfusion module with interactive tools to analyze and compare Computed Tomography Perfusion (CTP) and MR Perfusion (MRP) images of adult patients. Blood perfusion parameters are automatically calculated and displayed as a set of perfusion maps and perfusion tables. The perfusion tables include the calculation of parameters related to tissue flow (perfusion) and tissue blood volume. **The system contains a Diffusion Module with interactive tools to ease the process of analyzing and comparing MR Diffusion Weighted images (DWI) and MR Diffusion Tensor Imaging (DTI) of adult patients. This module is used to visualize local water diffusion properties from the analysis of diffusion- weighted MRI data.**

			The system supports Subtraction with interactive tools to aid with the analysis of Digital Subtraction Angiography (DSA) images in both interventional radiology and cardiology. Subtraction automatically subtracts a mask from contrast frames of an X-Ray Angiography study for visualization of vascular anatomy and pathology of adult patients.
Physical Characteristics	Software package	Software package	Software package
Data Source	MR Images	MR Images	MR Images
Technology and Output	- visualize local water diffusion properties - offers the Diffusion Tensor Imaging (DTI) maps including Fractional Anisotropy (FA) ADC/Mean Diffusivity (MD), Axial Diffusivity (AD), Radial Diffusivity (RD), Dxx, Dyy, Dzz, Dxy, Dxz, Dyz and color FA	- visualize local water diffusion properties - offers the capability to generate TENSOR data together with all other diffusion maps (including b0, ADC, TraceW, FA, AD, RD) from raw diffusion series.	- visualize local water diffusion properties - offers Diffusion Tensor Imaging of the following types Fractional Anisotropy (FA), Relative Anisotropy (RA), Volume Ratio (VR), ADC/Mean Diffusivity (ADC), Axial Diffusivity (AD), and Relative Diffusivity (RD).