Clarus Viewer Corporation
% Carolyn Guthrie
VP of Regulatory
Kapstone Medical, LLC
520 Elliot Street
CHARLOTTE NC 28202

February 24, 2023

Re: K222757
Trade/Device Name: Clarus Viewer®
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 25, 2023
Received: January 25, 2023

Dear Carolyn Guthrie:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222757

Device Name
Clarus Viewer®

Indications for Use *(Describe)*
Clarus Viewer® Version 1.0 is a software solution intended to be used for viewing, manipulation, communication, storage, 3D-visualization, and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports images and anatomical datasets, limited to CT and MR.

Clarus Viewer® supports the interpretation and evaluation of examinations and follow-up documentation of findings within healthcare institutions, for example, in Radiology and other Medical Imaging environments. It is intended to provide image and related information that is interpreted by a trained professional but does not directly generate any diagnosis or potential findings.

Note: The medical professional retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices. Clarus Viewer is a complement to these standard procedures. Clarus Viewer® is not intended for the displaying of digital mammography images for diagnosis.

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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Clarus Viewer® 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

1. Date of Preparation:

February 7, 2023

2. Applicant

Clarus Viewer Corporation
5030 Bradford Drive NW;
Building 2, Suite 104
Huntsville, AL 35805

3. Official Correspondent

Carolyn Guthrie
Email: cguthrie@kapstonemedical.com
Phone: (704) 737-2866
Kapstone Medical LLC
520 Elliot St.
Charlotte, NC 28202

4. Device Name

Trade Name: Clarus Viewer®

Common Name: Picture archiving and communications system
Classification Name: Medical Image Management and Processing System
Regulation Number: 21 CFR 892.2050
Product Code: LLZ
Classification: Class II
Panel: Radiology

5. Predicate Devices

Clarus Viewer® is substantially equivalent to the predicate device shown in Table 5.1.

Trade Name	Clearance	Claim of Equivalence for:	510(k) holder
ImmersiveTouch	K210726	Predicate Device	ImmersiveTouch

Table 5.1: Predicate devices

6. Intended Use (Intended Purpose and Conditions of Use):

Clarus Viewer® Version 1.0 is a software solution intended to be used for viewing, manipulation, communication, storage, 3D-visualization, and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports images and anatomical datasets, limited to CT and MR.

Clarus Viewer® supports the interpretation and evaluation of examinations and follow-up documentation of findings within healthcare institutions, for example, in Radiology and other Medical Imaging environments. It is intended to provide image and related information that is interpreted by a trained professional but does not directly generate any diagnosis or potential findings.

Note: The medical professional retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices. Clarus Viewer is a complement to these standard procedures. Clarus Viewer® is not intended for the displaying of digital mammography images for diagnosis.

7. Device Description

Clarus Viewer® is a stand-alone software package that imports medical data in the Digital Imaging and Communications and Medicine (DICOM) standard, stored on local or remote PACS sources. Clarus Viewer® is intended to allow users to visualize and manipulate 2D and 3D images and models of CT and MRI datasets and visualize and manipulate 3D volumetric models. Clarus Viewer® can present the 2D and 3D images in either a desktop mode or in Virtual Reality.

Within Clarus Viewer®, users can strip away layers of bone and tissue, revealing the relevant images for evaluation. Users can view and evaluate the 3D model from any angle. In the same way a doctor may hold and rotate a physical anatomical model in the real world, within Clarus Viewer® the image can be rotated and examined, or sliced away or apart to examine interior structures, tissues, and fluids.

The Clarus Viewer® system is intended to be used as a supplemental viewer by trained medical professionals. It allows the user to view images, models, and related medical information that can then be interpreted by a trained professional. Clarus Viewer® does not directly generate any diagnosis. The medical professional retains the ultimate responsibility for making the diagnosis.

Clarus Viewer is not intended for the displaying of digital mammography images for diagnosis.

8. Substantial Equivalence

8.1 Comparison of Intended Use

Clarus Viewer® and the predicate device are both stand-alone software intended for transfer of 2D medical imaging information to generate 3D representations for visualization, analysis, measuring and treatment planning. Thus, there is no difference between the subject device and the predicate device with respect to intended use.

8.2 Comparison of Operating Principle

Both Clarus Viewer® and the predicate device use 3D Generated Anatomical Representations in a 3D Space using the same VR hardware.

8.3 Comparison of Similar Technological Characteristics

Clarus Viewer® and the predicate device are both based on the following same technological characteristics:

- Both input DICOM medical data input.
- Both allow viewing in the Axial, Coronal and Sagittal planes.
- Both have MR and CT imaging modalities.
- Both utilize commercial VR hardware, namely VIVE Pro 2.
- Both utilize tracking with 6 degrees of freedom.
- Both have evaluation tools including annotation, measurement, and slicing.
- Both allow the increase and decrease of the model volumetric tissue densities.

8.4 Discussion of Technological Differences

There are new or different implementations of similar technological characteristics between Clarus Viewer® and the predicate device, with minor changes that do not affect the safety and effectiveness of the device. Clarus Viewer® and the predicate device have differences in the following technological characteristics:

- The imaging modalities of Clarus Viewer®, namely CT and MR, fall within that of the predicate, with the predicate also offering CBCT and 3D angiography.
- The VR Hardware Compatibility of the predicate includes the Oculus Quest 2 and VIVE Pro 2. Clarus Viewer® is only compatible with the VIVE Pro 2 and not compatible with the Oculus Quest 2.
- Both devices include Annotation, Measurement, Slice and Control Tools, and allow the modification of the transparency of the 3D representation which increases or decreases the volumetric model tissue densities for dynamic evaluation. Clarus Viewer® allows multiple methods for adjustment of transparency within the entire 3D representation or within specific portions only, while the predicate device adjusts the transparency for specific portions of the 3D representation only.

9. Performance Data

The following information is provided in support of substantial equivalence.

- Clinical evaluation, including:
  - Valid Clinical Association Assessment
  - Clinical Validation
  - Artifacts Analysis of the VIVE Pro 2
  - Image Display Quality Analysis of the VIVE Pro 2- contrast, resolution, luminance, distortion
- Risk Management activities
- Software testing, including unit testing, integration testing and system level testing of:
  - Virtual environment
  - User interface
  - Scan deck
  - Clarus data
  - Voxel model
  - Volumetric model
  - Clarus Viewer® tools
- Off-the-Shelf software validation
- Human Factors / Usability testing
- Cybersecurity assessment

11 Conclusion

Clarus Viewer® and the predicate device ImmersiveTouch (K210726) have the same intended use and are available by prescription only. Any technical differences identified do not result in new questions of safety or effectiveness.

Through assessment of technological characteristics, intended use and performance data, it can be concluded that Clarus Viewer is substantially equivalent to the ImmersiveTouch device.