May 27, 2026

Videomed Srl (a Baxter Healthcare Corp company)
Dania Di Pietro Paolo
Sr. Specialist, Regulatory Affairs
Via Cesare Battisti N. 31/C
Limena (Pd), 35010
Italy

Re: K254265
Trade/Device Name: Helion Viewer Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: [NOTE: Use date of most recent supplement]
Received: April 27, 2026

Dear Dania Di Pietro Paolo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254265

Please provide the device trade name(s).

Helion Viewer Suite

Please provide your Indications for Use below.

Helion Viewer Suite is a software device for displaying DICOM data and medical images.
It includes functions for image review, image manipulation, annotations, and 3D visualization (Multiplanar reconstructions and 3D volume rendering).

Helion Viewer Suite is not intended for primary image diagnosis or review of mammography images.
Helion Viewer Suite is not intended as the primary source for identification of surgical structures.
Helion Viewer Suite is not intended for performing any measurements for diagnostic, treatment, or therapy, but only for reference purposes

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Section 10.2 510(k) Summary

April 22, 2026

OWNER:

Videomed S.r.l (a subsidiary of Baxter Healthcare Corporation)
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Italy (EU)

CONTACT PERSON:

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IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Helion Viewer Suite
Common Name: DICOM Viewer
Classification Panel: Picture archiving and communications system (21 CFR 892.2050)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ

Table 1. Proposed Model number and Version Helion Viewer Suite

Model Number	Version Number	Name
116002	1.0	Helion Viewer Suite

Predicate Device

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Viewer	Brainlab AG	**K191014**	January 23, 2020

DESCRIPTION OF THE DEVICE

Helion Viewer Suite is a client-server application software for displaying and annotating 2D radiological images and 3D visualizations (Multi Planar Reconstruction MPR, 3D volume rendering). Helion Viewer Suite enables mobile and shared sessions for collaboration between healthcare professionals.

Helion Viewer Suite consists of two primary modules which also can be used independently.

o The Helion Fluid Touchless module supports the DICOM image viewer in the operating room using a touchless gesture-controlled monitor which is used throughout the surgery. The module is accessed on a Computer utilizing an external monitor.

o The Helion Anywhere Streaming module provides options for visualization of DICOM images exclusively before and after surgery. The module can be used on a Windows computer with monitor, mouse, and keyboard.

The software manages data and images acquired from DICOM compliant imaging systems.

Indications For Use

Helion Viewer Suite is a software device for displaying DICOM data and medical images.

It includes functions for image review, image manipulation, annotations, and 3D visualization (Multiplanar reconstructions and 3D volume rendering).

The Helion Viewer Suite is not intended for primary image diagnosis or review of mammography images.

The Helion Viewer Suite is not intended as the primary source for identification of surgical structures.

Helion Viewer Suite is not intended for performing any measurements for diagnostic, treatment, or therapy, but only for reference purposes.

Contraindications:

The Helion Viewer Suite is not intended for primary image diagnosis or review of mammography images.

The Helion Viewer Suite is not intended as the primary source for identification of surgical structures.

Helion Viewer Suite is not intended for performing any measurements for diagnostic, treatment, or therapy, but only for reference purposes.

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Device Comparison and Substantial Equivalence

Features	Predicate Device Cleared under K191014	Proposed Device Helion Viewer Suite	Assessment of Differences
Intended Use	Viewer is a software device for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements and 3D visualization (Multiplanar reconstructions and 3D volume rendering).	Helion Viewer Suite is a software for visualizing DICOM image data for investigation of the anatomy, for reference purposes.	The intended use of Helion Viewer Suite is more general than that of the predicate device, but the indications for use (see row below) remain the same. The proposed device IFU does not constitute a new Intended Use from the predicate device as both the predicate and the proposed devices are intended to review DICOM data for not diagnostic use. The use environment and use conditions are the same as the predicate device for which it is intended to be used.
Indications for Use	Viewer is a software device for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements and 3D visualization (Multiplanar reconstructions and 3D volume rendering). It is not intended for primary image diagnosis or the review of mammographic images.	Helion Viewer Suite is a software device for displaying DICOM data and medical images. It includes functions for image review, image manipulation, annotations, and 3D visualization (Multiplanar reconstructions and 3D volume rendering). The Helion Viewer Suite is not intended for primary image diagnosis or review of mammography images. The Helion Viewer Suite is not intended as the primary source for identification of surgical structures.	The measurement functionality of the proposed device is included in the word “annotations”. The proposed device has a limited scope in comparison to the predicate device, but the limitation in scope does not affect the intended use.

		Helion Viewer Suite is not intended for performing any measurements for diagnostic, treatment, or therapy, but only for reference purposes.	In summary, no safety or effectiveness concerns were identified for the proposed device.
Primary operating functions	Non-diagnostic viewing of medical images and other healthcare data in DICOM format.	Non-diagnostic viewing of medical images and other healthcare data in DICOM format.	Same
Intended Users	The device is generally used by medical professionals such as doctors, their assistants or nursing staff which are in need of displaying medical (DICOM) images and other healthcare data for non-diagnostic purposes.	The device is used by trained healthcare professionals such as surgeons or surgical teams responsible for displaying medical (DICOM) images and other healthcare data for non-diagnostic purposes.	Same
Patient population	The device is software which allows viewing of DICOM data. Hence there is no specific patient population.	The device is software which allows viewing of DICOM data. Hence there is no specific patient population.	Same
Operating principles	- On desktop PCs the interaction with the software is mainly performed with mouse and/or keyboard. - On touch screen PCs and on mobile devices the software is mainly used with a touch screen interface. - On Mixed Reality glasses the interaction is performed with a dedicated pointing device.	-On Windows PCs interaction with the software is mainly performed with mouse and/or keyboard. -On touch screen PCs interaction is intended to be performed with mouse and/or keyboard. - In the OR, the interaction is performed with a gesture recognition by means of a off the shelf sensor device.	The predicate device can be used also on touch screen PCs and on mobile devices with a touch screen interface. The system's limitation to specific platforms and the different interaction in the operating theater do not impact the safety and effectiveness of the device, and therefore, does not pose a risk to patients or users. This is because the device is intended for non-diagnostic purposes, and its functionality is not dependent on the underlying platform.

Sterile	N/A; software	N/A; software	N/A; software
Non-Pyrogenic	N/A; software	N/A; software	N/A; software

DISCUSSION OF NONCLINICAL TESTS:

Non-Clinical testing of Helion Viewer Suite has been performed against requirements for performance and safety, and to provide objective evidence that the device's intended use is met.

Non-Clinical testing was conducted on the Helion Viewer Suite software system to evaluate the functional performance of the device. Testing involved system level tests, performance tests and safety testing based on hazard analysis. Cybersecurity issues have been addressed.

Detailed summary information regarding the performance testing is supplied in following sections

- Performance Testing: Bench Testing
- Software Documentation: Software Verification and Validation Testing within the eSTAR submission documentation.

Specifically, non-clinical performance testing was performed to verify the accuracy of measurement and annotation functions used for reference purposes. Verification and validation activities assessed distance, angle and Cobb angle, area, point, circle, and ellipse measurements using standardized phantom datasets and controlled synthetic test images with known reference values. Distance measurements were verified within a tolerance of ±0.1 cm; angle and Cobb angle measurements within ±1 degree; area measurements for circles and ellipses within ±1%; and point, circle, and ellipse HU value annotations within ±1 unit.

All measurement functions met predefined acceptance criteria and demonstrated repeatable performance, with no failures or deviations identified that would impact safety or effectiveness.

In addition to the verification and validation testing activities executed byVideomed srl to establish the performance and functionality of the Helion Viewer Suite, several standards were utilized to verify safety and efficacy of the device:

General Use Standards:

ISO 14971 – Medical Devices – Application of Risk Management to Medical Devices

IEC 62366-1 - Medical devices - Part 1: Application of usability engineering to medical devices

IEC 62304- Medical device software – Software life cycle processes

ISO 15223-1 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

NEMA PS 3.1 - 3.20 2024e: Digital Imaging and Communications in Medicine (DICOM) Set

Baxter/Videomed Srl referred as well to the following guidance documents:

Guidance for Industry: Content of Premarket Submissions for Device Software Functions

Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff

Guidance for Industry – Applying Human Factors and Usability Engineering to Optimize Medical Device Design

Guidance for Industry– Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software

Guidance for Industry- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Guidance for Industry- Postmarket Management of Cybersecurity in Medical Devices

Guidance for Industry- Off the Shelf Software Use in Medical Devices

CONCLUSION:

The Helion Viewer Suite has been verified and validated against design input requirements, user needs and intended uses. The non-clinical data demonstrate that the subject device raises no new questions concerning safety and effectiveness, is substantially equivalent, and performs comparably to the predicate device that is currently marketed for the same intended use.