



Augmedit B.V.
Claartje Ypma
CEO
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Naarden, Noord-Holland 1411 LH
Netherlands

September 10, 2024

Re: K240094
Trade/Device Name: LumiNE US; Lumi
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 12, 2024
Received: August 1, 2024

Dear Claartje Ypma:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and

production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the FDA logo.

Jessica Lamb, PhD
Assistant Director, Imaging Software Team
DHT8B: Division of Radiologic 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

510(k) Number (if known)

K240094

Device Name

LumiNE US

Indications for Use (Describe)

The LumiNE US software is intended for the visualization of medical images to provide insights in anatomy and pathology in preparation of surgical treatment. As such, the software allows for the conversion of 2D patient imaging into 3D models and for the visualization of 2D and 3D patient imaging including Augmented Reality. When accessing the LumiNE US software from a wireless Head-Mounted Display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use.

The LumiNE US software is intended for use by a (neuro)surgeon, (neuro)surgical resident or a medical professional that is qualified by a hospital to prepare medical imaging for surgeons. For the conversion of medical imaging into 3D models, Magnetic Resonance Imaging (MRI) and/or Computed Tomography (CT) imaging of adult patients are required. The LumiNE US software is intended to be used for visualization in preparation of surgery, and not for diagnostic use. Therefore, segmentation and visualization of tumors or any other pathology can only be used for previously known and pre-diagnosed conditions.

LumiNE US can only be used for contrast-enhanced T1 MR scans (semi-automatic segmentation of known tumor, skin, brain, and ventricles), or for CT scans (threshold-based segmentation).

The LumiNE US MRI T1 tumor segmentation function can only be used in case of a single intracranial contrast enhancing tumor, diagnosed by a neuroradiologist or a neurosurgeon, with a minimal volume of 2.0 cc (0.1 in³) and a minimal diameter in any direction of 15 mm (0.6 inch), and a maximum volume of 100cc (6.1 in³) and a maximal diameter in any direction of 75 mm (3.0 inch).

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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510(k) Summary

Contact Information	
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Summary date:	September 10, 2024

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1 Subject Device Names

Name of device: **LumiNE US**

Trade name: **LumiNE US, Lumi**

2 Predicate Device Information

Trade or proprietary or model name: **VSI Holomedicine**

Original Applicant: **ApoQlar GmbH**

510(k) Number: **K213215**

Regulation Number: **21 CFR 892.2050**

3 Description of the Device

LumiNE US is a software device for the visualization of medical images to provide insights in anatomy and pathology in preparation of surgical treatment. As such, the software allows for the conversion of 2D patient imaging into 3D models and for the visualization of 2D and 3D patient imaging including Augmented Reality. When accessing the LumiNE US software from a wireless Head-Mounted Display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. Applicable pathology includes scans with known intracranial lesions that are diagnosed as Glioblastoma, Meningioma, or Metastasis by a neurosurgeon or neuroradiologist.

4 Indications for Use

The LumiNE US software is intended for the visualization of medical images to provide insights in anatomy and pathology in preparation of surgical treatment. As such, the software allows for the conversion of 2D patient imaging into 3D models, and for the visualization of 2D and 3D patient imaging including Augmented Reality. When accessing the LumiNE US software from a wireless Head-Mounted Display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use.

The LumiNE US software is intended for use by a (neuro)surgeon, (neuro)surgical resident or a medical professional that is qualified by a hospital to prepare medical imaging for surgeons. For the conversion of medical imaging into 3D models, Magnetic Resonance Imaging (MRI) and/or Computed Tomography (CT) imaging of adult patients are required. The LumiNE US software is intended to be used for visualization in preparation of surgery, and not for diagnostic use. Therefore, segmentation and visualization of tumors or any other pathology can only be used for previously known and pre-diagnosed conditions.

LumiNE US can only be used for contrast-enhanced T1 MR scans (semi-automatic segmentation of known tumor, skin, brain, and ventricles), or for CT scans (threshold-based segmentation).

The LumiNE US MRI T1 tumor segmentation function can only be used in case of a single intracranial contrast enhancing tumor, diagnosed by a neuroradiologist or a neurosurgeon, with a minimal volume of 2.0 cc (0.1 in³) and a minimal diameter in any direction of 15 mm (0.6 inch), and a maximum volume of 100cc (6.1 in³) and a maximal diameter in any direction of 75 mm (3.0 inch).

5 Substantial Equivalence Comparison Summary

5.1 Substantial equivalence comparison table

The following table provides a comparison of the subject device's characteristics and functionality with respect to the identified predicate device.

Device characteristics	Subject device	Predicate device	Comparison analysis
Device name	LumiNE US	VSI Holomedicine	N/A
510(k) number	K240094	K213215	N/A
Manufacturer	Augmedit B.V.	apoQlar GmbH	N/A
Medical specialty	Radiology	Radiology	Identical
CFR Reference	21 CFR 892.2050	21 CFR 892.2050	Identical
Device classification name	Medical Image management and Processing System	Medical Image management and Processing System	Identical
Common name	Automated Radiological Image Processing Software	Radiological Image Processing System	Substantially equivalent, the subject device has a more specific common name because of the presence of nonadaptive machine learning algorithms.
Product code	QIH	LLZ	Substantially equivalent, the subject device has a more specific product code because of the presence of nonadaptive machine learning algorithms.
Intended use/Indications for use	The LumiNE US software is intended for the visualization of medical images to provide insights in anatomy and pathology in preparation of surgical treatment. As such, the software allows for the conversion of 2D patient imaging into 3D models, and for the visualization of 2D and 3D patient imaging including Augmented Reality. When accessing the LumiNE US software from a wireless head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. The LumiNE US software is intended for use by a (neuro)surgeon, (neuro)surgical resident or a medical professional that is qualified by a hospital to prepare medical imaging for surgeons. For the conversion of medical imaging into 3D models, Magnetic Resonance Imaging (MRI) and/or Computed Tomography (CT) imaging of adult patients are required. The LumiNE US software is intended to be used for visualization in preparation of surgery, and not for diagnostic use. Therefore, segmentation and visualization of pathology can only be used for previously known and pre-diagnosed conditions. LumiNE US can only be used for contrast-enhanced T1 MR scans (semi-automatic segmentation of known	VSI HoloMedicine® is a software device for displaying digital medical images acquired from CT, Angio CT, MRI, CBCT, PET, and SPECT sources. It is intended to visualize 3D imaging holograms of the patient for pre-operative planning outside and/or inside the surgical room. When accessing VSI HoloMedicine® from a wireless head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. VSI HoloMedicine® is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.	Substantially equivalent

Device characteristics	Subject device	Predicate device	Comparison analysis
	tumor, skin, brain, and ventricles), or for CT scans (threshold-based segmentation). The LumiNE US MRI T1 tumor segmentation function can only be used in case of a single intracranial contrast enhancing tumor, diagnosed by a neuroradiologist or a neurosurgeon, with a minimal volume of 2.0 cc (0.1 in ³) and a minimal diameter in any direction of 15 mm (0.6 inch), and a maximum volume of 100cc (6.1 in ³) and a maximal diameter in any direction of 75 mm (3.0 inch).		
Prescription use	Yes	Yes	Identical
Patient population	The device specifically focuses on visualization of medical images and preparation of surgical treatment, for patients at the age of 22 or older	The device is a software which allows for viewing of DICOM data. Therefore, its intended use is without any restrictions regarding patient population	Different, but no impact on safety and effectiveness.
Main system components	- Cloud based storage of patient data (including anonymizer) and viewer - Microsoft HoloLens 2 - Browser based (universal) mobile device viewer	- Cloud based storage for patient data - Microsoft HoloLens 2 - Streaming hardware hub to connect image modalities directly to Microsoft HoloLens 2 - Anonymizer (for video's)	Substantially equivalent
Imaging modality	- MRI - CT	- CT - angio CT - MRI - CBCT - PET CT - SPECT CT	Substantially equivalent, the subject device uses MRI and CT imaging data, while the predicate device allows to use a broader range of imaging modalities. Thus, the predicate device allows to view more data types in the HoloLens.
Data Type Supported	- DICOM 3D formats: STL GLTF - PDF - JPEG - PNG	- DICOM 3D formats: OBJ, STL - PDF - JPEG - PNG - MP4	Substantially equivalent, both the subject device as well as the predicate device support DICOM imaging as well as 3D format types. The predicate device additionally supports data types which allow video streaming.
	3D view in web browser	General manipulation in HoloLens (grab, move,	Substantially equivalent:

Device characteristics	Subject device	Predicate device	Comparison analysis
Image view/manipulation	- Fusion of 3D objects with source image data (web browser and Microsoft HoloLens 2) - General manipulation in HoloLens (grab, move, zoom, hide, change color etc.) - Surgical preparation tools which allow markings on 3D models in Microsoft HoloLens 2 - Sharing (remote and co-located)	zoom, hide, change color etc.) - Surgical Preparation Tools (draw, measure, etc). - Sharing (remote, but not co-located).	- Both the predicate device and Lumi enable marking on 3D models in HMD for planning purposes. - Lumi allows for saving revisions on 3D models (both web and Microsoft HoloLens 2) - Lumi allows validation of 3D models.
Communication between headset and computer	- Web browser (computer) and Microsoft HoloLens 2 connect to cloud environment. - Wireless encrypted connection with Microsoft HoloLens 2.	- Web browser (computer) and Microsoft HoloLens 2 connect to cloud environment. - Wireless encrypted connection with Microsoft HoloLens 2. Hardware to stream data from image acquisition system directly to Microsoft HoloLens 2.	Substantially equivalent, VSI uses additional hardware to connect to image acquisition systems. Communication for both the subject as well as the predicate device is wireless, and data encrypted.
MPR viewing	Yes, for CT, MRI	This viewing feature enables the display of CT, MRI, CBCT, Angio CT, PET CT and SPECT CT images into axial, coronal and sagittal orientations	Substantially equivalent for CT and MRI.
3D Volume rendered viewing	3D volume rendering in web browser. - Option to create manual segmentation to visualize results in Microsoft HoloLens 2.	3D perspective views of CT, MRI, CBCT, Angio CT, PET CT and SPECT CT images sets that have been transformed into volumes. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features.	Different, but no impact on safety and effectiveness. Both the subject as well as predicate device present 2D imaging information in 3D, however, the predicate device does not include image segmentation functionality.
Surgical planning	Creating and saving of 3D models and marks thereon on HMD for planning purposes.	Saving and loading configurations of medical images, marks, and 3D models on HMD. Ability to save and load combinations and arrangement of objects displayed in the 3D space on HoloLens for planning purposes. Possibility to create annotation like drawings.	Substantially equivalent
Transmission modes	Web browser (computer) and Microsoft HoloLens 2 connect via wireless encrypted	Web browser (computer) and Microsoft HoloLens 2 connect via wireless encrypted	Substantially equivalent

Device characteristics	Subject device	Predicate device	Comparison analysis
	connection to cloud environment.	connection to cloud environment.	
Verification and validation	Software verification and validation was performed and demonstrates that the LumiNE US software performs as intended in the specified use conditions. Documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff 'Content of Premarket Submissions for Device Software Functions'. In addition, non-clinical testing was performed to evaluate the performance of the semi-automated segmentation algorithm against manual segmentation data. Visual quality testing on software using the Microsoft HoloLens 2 Head-Mounted Display has been performed. Non-clinical and clinical data demonstrate that the LumiNE US software is as safe, as effective, and performs as well as the legally marketed device predicate.	Visual quality testing on software using the Microsoft HoloLens Headset has been performed. Non-clinical and clinical data demonstrate that VSI Holomedicine is as safe, as effective, and performs as well as the legally marketed device predicate. Software verification and validation demonstrate that the VSI Holomedicine should perform as intended in the specified use conditions.	Substantially equivalent

5.2 Similarities between the Subject Device and the Predicate Device

Both the subject device and the predicate device share the same indications for use. Both devices are intended for the visualization of medical images in preoperative planning. They enable the conversion of 2D imaging information into 3D and virtually visualize the 3D models, and as such provide additional insights into anatomy and pathology. Both devices are intended for visualization purposes only and are not intended for diagnostic use.

Thus, both the subject and predicate device include surgical planning tools which allow for the preparation of surgical treatment.

The subject device as well as the predicate device make use of a secure cloud environment to store original image data and visualization settings. In addition, for both devices, the cloud platform connects with Microsoft HoloLens 2 which allows visualization of 3D virtual images.

5.3 Differences between the Subject Device and the Predicate Device

The subject device is different from the predicate device, in that the predicate device allows the use of a broader range of imaging modalities, has no restrictions regarding patient population and supports video streaming in addition to DICOM and 3D format type data. These differences do not impact the safety and effectiveness of the subject device.

The subject device uses a different method for visualization of 2D images in 3D: where the predicate device uses volume rendering, the subject device allows image segmentation. This difference does not impact the safety and effectiveness of the subject device compared to the predicate. Reference is made to performance testing provided in the Performance section of this submission where results of the semi-automatic image segmentation algorithm are compared to manual segmentation data, created and reviewed by an expert panel of clinical specialists.

6 Summary of Performance Testing

Aside from the verification testing conducted as part of the software life cycle development process, additional performance testing was performed on key elements of our software to demonstrate that the device is safe and effective. A total of 9 nonclinical tests were performed as part of this submission. This section provides a summary of the tests.

1. The performance of the semi-automatic segmentation function (T1cSF) was tested on a representative dataset, including data from the U.S. and outside the U.S. Analysis showed clinically acceptable accuracy for both the total test set and the U.S. subset (a more detailed summary is provided in Paragraph 8 of this 510(k) Summary).
2. The manual segmentation function was compared to 3D models generated using a third party software program. A high similarity was found between the systems.
3. In accordance with the IEC standards (IEC63145-20-20 and 63145-20-10) on contrast, optical distortion, luminance and spatial resolution, the visual quality of the head mounted display was tested to ensure that the device provides users with authentic and reliable virtual images.
4. DICOM visualization tests were performed to evaluate the features related to the manipulation of scans in the software.
5. The latency of the Multiplayer feature was tested to ensure it stays within acceptable limits, providing users with reliable and timely updates when using this function.
6. Multiple DICOM variants and scanners were tested to identify which DICOM variations are supported by the LumiNE US software, and which are not.
7. Testing that the dimensions of 3D virtual images, displayed using the Microsoft HoloLens 2 head mounted display, correspond with their real-world counterparts.
8. Testing the ability of the head mounted display to render colors accurately.
9. Testing the usability of the software by means of performing a Moderated Task Analysis (MTA).
10. Testing the STL import functionality to demonstrate users can safely upload and associate 3D models .in STL format to the exact same scan from which they were created

7 Validation of Machine Learning Algorithms

This section provides a summary of the validation of machine learned algorithms used in our submission as requested by FDA during review of the 510(k). The LumiNE US MRI T1 tumor segmentation function (T1cSF)

transforms contrast enhanced T1-weighted MR images (MRI-T1) of the head into 3D models of the skin, brain, tumor and ventricles, and therefore contains 4 algorithms.

The algorithms were originally trained using machine learning (nnUnet). To validate the T1cSF for application in the U.S., and incorporation in the Augmedit LumiNE US software, a specific independent U.S. test dataset of MRI-T1 scans was created with each scan belonging to a unique patient. This set was not used for training of the T1cSF algorithms. The inclusion criteria for this dataset were:

1. Patient age of minimally 22 years
2. T1 weighted, contrast-enhanced MRI scan
3. Scan of the cranium from vertex to minimally foramen magnum level and maximally C2 level
4. Scan with more than 100 slices
5. Scan with maximum slice thickness of 2 mm
6. Scan with maximum slice interval of 2mm
7. Scan contains minimally 1 and maximum 4 intracranial lesions which are diagnosed as Glioblastoma, Meningioma, or Metastasis by a neurosurgeon or neuroradiologist with a minimal volume of 0.5 cc (0.06 in³), and a minimal diameter in any direction 0.5 cm (0.20 inch)

The selected U.S. data were collected from institutions covering a wide range of regions across the U.S., from the West Coast to the East Coast and the Southern region. The U.S. data includes a diverse set of patients from different regions and ethnic backgrounds. When compared to the U.S. Census Bureau 2023 data, the demographic distribution of the test set reflected the U.S. general population. Each U.S. center contributed to the ethnic diversity of the dataset.

The Dice Similarity Coefficient (DSC) and the 95% Hausdorff Distance (95% HD) were chosen as evaluation metrics because the DSC and the 95% HD are among the most commonly used metrics for evaluating the quality of medical image segmentation algorithms. The Dice score measures the overlap between the predicted segmentation and the ground truth, providing a straightforward way to assess segmentation accuracy. The 95% HD, on the other hand, measures the distance between the boundaries of the predicted and actual segmentations, focusing on the worst-case errors while mitigating the impact of outliers.

First the required sample size for the U.S. test was determined for each structure (skin, brain, tumor and ventricle). Using the DSC, the required number of scans was calculated to establish non-inferiority compared to the European dataset (publicly available (<https://doi.org/10.1007/s00701-024-05973-8>)). Thereby also minimally acceptable criteria per metric per structure were determined. Thereby the following acceptance criteria were chosen:

1. DSC: For tumor segmentation, a DSC above 0.80 was considered acceptable. For skin and brain, a DSC above 0.90 was considered acceptable. For ventricles a DSC above 0.85 was considered acceptable.
2. 95% HD: For brain, skin and ventricle segmentation a 95% HD of below 10 mm was considered as acceptable. For tumor, a 95%HD of 15 mm or below was considered as acceptable.

The U.S data was individually truthed by 3 U.S. based neurosurgeons with relevant experience including fellowships. The definitive US ground truth test set was established by mutual agreement after internal discussion and signed off per scan per truther.

Results were analyzed using the median dependent on data distribution in the subgroup. For each structure, all results were statistically non-inferior compared to the European test set data. Thereby all DSC and 95% HD results were shown to be within preset limits:

1. DSC: median values including 95% CI were above the acceptance criterium in all structures; **For brain**, the 95% CI of the median Dice (0.96, 95% CI 0.95-0.97) was totally above the established criterium (Dice 0.9). **For skin**, the 95% CI of the median Dice (0.99, 95% CI 0.99-0.1) was totally above the established criterium (Dice 0.9). **For tumor**, the 95% CI of the median Dice (0.93, 95% CI 0.92-0.94) was totally above the established criterium (Dice 0.8). **For ventricles**, the 95% CI of the median Dice (0.89, 95% CI 0.85-0.91) was totally above the established criterium (Dice 0.85).

2. 95% HD: median values including 95% CI were below the acceptance criterium in all structures. **For brain**, the 95% CI of the median 95% HD (5.88, 95% CI 4.75-8.39) was totally below the established criterium (10 mm). **For skin**, the 95% CI of the median 95% HD (3.36, 95% CI 0.99- 5.51) was totally below the established criterium (10 mm). **For tumor**, the 95% CI of the median 95% HD (2.85, 95% CI 1.82- 4.12) was totally below the established criterium (15 mm) and also below 10 mm. **For ventricles**, the 95% CI of the median 95% HD (1.93, 95% CI 1.70-2.92) was totally below the established criterium (10 mm).



An analysis was performed to compare an EU sample to the US sample, and this demonstrated non-inferiority for DSC and HD95 across the four applicable segmented structures.

We subsequently performed a more detailed subgroup analysis of the general T1cSF segmentation performance in all 4 categories (brain, skin, tumor, ventricles) according to gender, race/ethnicity, tumor type, scanner model, magnetic field strength, scan quality and institution. This did not show any influence to T1cSF segmentation quality in this U.S. test set.

We subsequently performed a more detailed subgroup analysis of the T1cSF tumor segmentation performance according to Size/Volume, Number of lesions and Location.

1. Size/Volume: We observed that the subgroups with 'Tumor Volume = 0-2cc' and 'Biggest Lesion's Max Diameter = 0-15mm' showed DSC and/or 95% HD results below the acceptance criteria. These subgroups also contained many of the outliers. We thereby found insufficient data for tumors larger than 100cc or with a max diameter exceeding 75mm.
2. Number of Lesions: We also observed a lack of sufficient data to validate the performance of scans with multiple lesions.
3. Location: We observed an equally distributed performance across regions and side.

Based on the results above, the LumiNE US T1cSF can thereby be used for tumor segmentation only in case of a single intracranial contrast enhancing tumor, diagnosed by a neuroradiologist or a neurosurgeon, with a minimal volume of 2.0 cc (0.1 in³) and a minimal diameter in any direction of 15 mm (0.6 inch), and a maximum volume of 100cc (6.1 in³) and a maximal diameter in any direction of 75 mm (3.0 inch).

8 Application of Standards

The following standards are applicable to the LumiNE US software:

- EN ISO 13485:2016/A11:2021 Medical devices - Quality management systems
- ISO 14971:2019 Medical devices – Application of Risk Management to Medical Devices (Recognition number: 5-125)
- EN 62304:2006+A1:2015 Medical Device software- Software Life-Cycle Processes (Recognition number: 13-79)

LumiNE US software passed all testing. Details and reports are included in Section Software/Firmware and Cybersecurity and Interoperability and Section Performance Testing. The testing performed demonstrates that the subject device, LumiNE US software, meets all requirements. It meets the requirements of international and US standards for safety and performance.

The Declarations of Conformity to the above listed standards are provided in the Administrative Section of this submission.

There is no additional Electrical safety information applicable for this submission.

Finally, the following FDA guidance Documents were used during preparation of this 510(k) submission:

- Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff; June 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff; September 27, 2023