



June 22, 2026

Cercare Medical A/S
% Jennifer Willner
President
JW Regulatory Consulting, LLC
406 Wacouta St., Unit 417
Saint Paul, Minnesota 55101

Re: K260316

Trade/Device Name: CMN Capillary Function with Oncology Virtual Expert
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: May 14, 2026
Received: May 14, 2026

Dear Jennifer Willner:

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.
Assistant Director
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

Indications for Use

510(k) Number (if known)

K260316

Device Name

CMN Capillary Function with Oncology Virtual Expert

Indications for Use (Describe)

Cercare Medical Neurosuite (CMN) and associated modules is an image processing software package to be used by trained professionals, including physicians and medical technicians.

The CMN software package runs on standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM (Digital Imaging and Communications in Medicine) compliant imaging devices. CMN provides viewing capabilities of datasets acquired with MRI and CT.

The Capillary Function module provides analysis capabilities for functional and dynamic imaging datasets acquired with MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT). The Capillary Function module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. In addition, the Capillary Function module's DWI technology is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.

Oncology Virtual Expert is intended for semi-automatic labeling, visualization, and volumetric quantification of brain glioma (WHO Grade II through IV), including glioblastoma (WHO Grade IV), astrocytoma (WHO Grade II, III, and IV), and oligodendroglioma (WHO Grade III), from a set of standard MRI images of adult patients who are known to have pathologically proven glioma. Volumetric measurements may be automatically compared to prior measurements when available; to minimize measurement variability, such longitudinal comparisons should be performed using the same scanner model and consistent acquisition parameters. Oncology Virtual Expert is not to be used for primary diagnosis and is intended to be used by trained professionals as an additional source of information for decision support.

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

510(k) Number: K260316

Date Prepared: June 17, 2026

Table 1: Submitter Information

Manufacturer: Cercare Medical A/S Inge Lehmanns Gade 10 DK-8000 Aarhus C Denmark US FDA ERN: 3019844085	Manufacturer's Contact Person: Mikkel Bo Hansen Chief Scientific Officer Phone: +45 22890125 Email: mbh@cercare-medical.com
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Table 2: Device Information

Trade Name	CMN Capillary Function with Oncology Virtual Expert
Common Name	CMN Capillary Function with Oncology Virtual Expert
Classification Name	Medical Image Management and Processing System
Regulation	21 CFR 892.2050
Product Code	QIH & LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology (OHT8)

CMN Capillary Function with Oncology Virtual Expert is substantially equivalent to the NS-HGlio Predicate Device (**Table 3**) and its base platform (CMN Capillary Function) is identical to the base platform of the CMN Capillary Function with Virtual Expert Reference Device (**Table 4**). Neither of these have been subject to a design-related recall.

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
NS-HGlio	Neosoma, Inc.	K221738

Table 4: Reference Device

Predicate Device	Manufacturer	FDA 510(k)
CMN Capillary Function with Virtual Expert	Cercare Medical A/S	K241989

Device Description

Cercare Medical Neurosuite is a software-only device designed to streamline medical image processing by providing for the visualization and study of medical images. CMN can be installed on a customer PC, or it can be accessed remotely using remote desktop technologies. CMN provides viewing, quantification, analysis and reporting capabilities. CMN is not intended as a dedicated PACS system for long term persistent storage of patient data.

CMN is software that is intended for use by trained professionals, including physicians and medical technicians. The software provides cerebral image processing capabilities for providing important clinical markers in time-critical management of suspected acute ischemic stroke patients. CMN is intended to be used as decision support software only and the clinician continues to provide all treatment decisions.

The software is intended to visualize and study neuroimaging by image viewing and registration of medical images. CMN works with MRI (Magnetic Resonance Image) and CT (computed tomography) technologies.

CMN accepts and produces data sets in the DICOM format. DICOM is a standard format for storing and transmitting medical image data in vendor neutral format and is managed by the DICOM Standards Committee. CMN also supports DICOM Structured Reporting (DICOM SR) for documenting quantitative results of study analyses.

CMN is a platform that allows for the addition of certain modules for further analysis, including Capillary Function and Oncology Virtual Expert modules. The CMN platform and Capillary Function module are identical to the Reference Device (K241989) while the Oncology Virtual Expert module is the subject of this premarket application.

Oncology Virtual Expert

Oncology Virtual Expert, when added to the installed CMN Capillary Function, provides further functionalities for reading, writing, visualizing and other functionalities for studying medical images.

Oncology Virtual Expert provides post-processing technologies that allow for delineation and volumetric quantification of perceived pathological tissue that may be related to neuro oncology, based on primary acquired MRI data including T1 images acquired pre- and post-contrast and T2FLAIR images. The output provides information that can be used to assess the volume of pathological tissue for a patient.

Oncology Virtual Expert also allows for extraction of information from other images within the segmented tumor lesions, such as the mean value and standard deviation for, e.g., perfusion images obtained through the Capillary Function module. This information, as well as volumetric information, can be generated as aggregated views across multiple imaging studies for a given patient.

The output maps generated can be viewed by standard DICOM image viewers. The Oncology Virtual Expert works with the following technologies:

- MRI (Magnetic Resonance Image)

Indications for Use

Cercare Medical Neurosuite (CMN) and associated modules is an image processing software package to be used by trained professionals, including physicians and medical technicians.

The CMN software package runs on standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM (Digital Imaging and Communications in Medicine) compliant imaging devices. CMN provides viewing capabilities of datasets acquired with MRI and CT.

The Capillary Function module provides analysis capabilities for functional and dynamic imaging datasets acquired with MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT). The Capillary Function module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. In addition, the Capillary Function module's DWI technology is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.

Oncology Virtual Expert is intended for semi-automatic labeling, visualization, and volumetric quantification of brain glioma (WHO Grade II through IV), including glioblastoma (WHO Grade IV), astrocytoma (WHO Grade II, III, and IV), and oligodendroglioma (WHO Grade III), from a set of standard MRI images of adult patients who are known to have pathologically proven glioma. Volumetric measurements may be automatically compared to prior measurements when available; to minimize measurement variability, such longitudinal comparisons should be performed using the same scanner model and consistent acquisition parameters. Oncology Virtual Expert is not to be used for primary diagnosis and is intended to be used by trained professionals as an additional source of information for decision support.

Technological Characteristics

CMN Capillary Function with Oncology Virtual Expert is image processing software for cerebral image processing, capable of generating regions of interest for tissue potentially affected by neuro oncology. The image processing software generates maps of assessed neuro oncology, intended to be used during management of brain tumors as decision support.

It is emphasized that the output from the software should not be used without close scrutiny of the relevance to the patient in question, including all available evidence and quality checking of the appropriateness of the output.

All result images generated by any module (Capillary Function or Oncology Virtual Expert) are handled and stored by the CMN, which can expose the data to the end user via the associated graphical user interface or via network communication to other hospital IT systems such as local picture archive and communication systems (PACS).

The Oncology Virtual Expert constitutes the following list of primary functionalities:

- Delineation of neuro oncology lesions, including imaging-based tissue classifications: T2/FLAIR hyperintensity and T1 enhancing tissue (US market); T2/FLAIR hyperintensity, T1 enhancing tissue, and necrotic tissue (non-US markets)
- Volumetric analysis of the individual tissue classifications
- Longitudinal comparison of tumor volumes if more than one MRI study is available
- Automatic extraction of perfusion data from each lesion type
- Automatic reporting of results in the DICOM format

The Predicate Device provides equivalent estimates of the primary clinically relevant features offered by the Oncology Virtual Expert, concerning

- Delineation and volumetric analysis of contrast enhancing region
- Delineation and volumetric analysis of edematous tissue
- Collection and reporting of volumetric data across time if more studies exist for the same patient
- Computation of perfusion metrics within the different tissue classes

Note that the first three items are all part of both the Subject Device and Predicate Device, whereas the latter is a unique data collection and reporting feature for the Subject Device.

Differences in Technical Characteristics/Performance with Respect to the Predicate Device

CMN Capillary Function with Oncology Virtual Expert and the Predicate Device (K221738) both apply to the field of neuro oncology (brain cancer) and are indicated for a subset of primary brain tumors, specifically brain glioma (WHO Grade II through IV).

The Subject Device is identical to the Predicate Device with the exception of the following features:

- The Subject Device does not rely on off-premises resources to perform operations, which is in contrast to the cloud-based mode of operation required by the Predicate Device

The Subject and Predicate devices are based on the same technological elements of viewing, processing and analyzing DICOM image data to assist the clinician during diagnostic procedures. These differences do not impact the intended use or raise new questions with the safety and performance of the device.

Performance Standards

CMN Capillary Function with Oncology Virtual Expert has been developed in conformance with the following standards and FDA guidance, as applicable:

- ISO 13485:2016, Quality management systems – Requirements for regulatory purposes
- ISO 14971:2019, Medical devices – Application of risk management to medical devices

- IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 62304:2015, Medical device software – Software lifecycle processes
- IEC 82304-1:2016, Health Software Part 1: General Requirements for Product Safety
- ISO 15223-1:2021, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- ISO 20417:2021, Medical devices – Information to be supplied by the manufacturer
- NEMA PS 3.1-3.20:2024, Digital Imaging and Communications in Medicine (DICOM)
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions, September 2022

Performance Data

CMN Capillary Function with Oncology Virtual Expert complies with DICOM (Digital Imaging and Communications in Medicine), developed by the American College of Radiology and the National Electrical Manufacturers Association – NEMA PS 3.1-3.20.

Cercare conducted extensive performance validation testing and software verification and validation testing of the CMN Capillary Function with Oncology Virtual Expert. This performance validation testing demonstrated that the CMN system provides accurate representation of key processing parameters under a range of clinically relevant parameters associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the CMN system met all design requirements and specifications.

Comparative performance testing was performed for the Subject Device with respect to the Predicate Device using a 100-patient subset (425 studies) of the MU-Glioma Post dataset (University of Missouri). Both devices were independently compared against the same expert manual segmentation ground truth, established through a STAPLE-based consensus algorithm with three-tiered expert review including final consensus approval by two board-certified neuroradiologists. The comparison study population comprised: glioblastoma (n=73), astrocytoma (n=16), diffuse glioma (n=8), oligodendroglioma (n=2), and pilocytic astrocytoma (n=1), acquired predominantly on Siemens MRI systems at 1.5T and 3.0T field strengths. Testing the Predicate and Subject devices demonstrated equivalent estimates of the primary clinically relevant features offered by Oncology Virtual Expert, concerning

- Delineation and volumetric analysis of T1 enhancing region (mean Dice similarity coefficient: Subject Device 0.706, Predicate Device comparable)
- Delineation and volumetric analysis of T2/FLAIR hyperintensity region (mean Dice similarity coefficient: Subject Device 0.822, Predicate Device comparable)

- Collection and reporting of volumetric data across time if more studies exist for the same patient and quantification of imaging-based progression assessment

Subgroup analyses demonstrated consistent performance across scanner manufacturers (Siemens, GE, Philips), field strengths (1.5T and 3.0T), tumor types, and lesion size categories. Performance increased with lesion volume, as expected from the properties of the Dice similarity metric. Device labeling instructs users that longitudinal volumetric comparisons should be performed using the same scanner model and consistent acquisition parameters to minimize measurement variability.

Together with software verification and validation, the performance validation demonstrated that CMN Capillary Function with Oncology Virtual Expert satisfies all design requirements and device specifications and is substantially equivalent to the Predicate Device.

Substantial Equivalence

In comparison with the Predicate NS-HGlio device (K221738) and Reference CMN Capillary Function with Virtual Expert device (K241989), CMN Capillary Function with Oncology Virtual Expert has the same intended use and similar indications, technological characteristics and principles of operation as described in the comparison table below.

Table 5: Substantial Equivalence Comparison Table

Description	Subject Device	Predicate Device (K221738)	Reference Device (K241989)	Conclusion
Product Name	CMN Capillary Function with Oncology Virtual Expert	NS-HGlio	CMN Capillary Function with Virtual Expert	
Manufacturer	Cercare Medical A/S	Neosoma, Inc.	Cercare Medical A/S	
Product Code / Regulation	QIH & LLZ / 21CFR 892.2050	QIH / 21CFR 892.2050	LLZ / 21CFR 892.2050	Same
Indications for Use	<p>Cercare Medical Neurosuite (CMN) and associated modules is an image processing software package to be used by trained professionals, including physicians and medical technicians.</p> <p>The CMN software package runs on standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM (Digital Imaging and Communications in Medicine) compliant imaging devices. CMN provides viewing capabilities of datasets acquired with MRI and CT.</p> <p>The Capillary Function module provides analysis capabilities for functional and dynamic imaging datasets acquired with MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT). The Capillary Function module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This</p>	<p>NS-HGlio is intended for the semi-automatic labeling, visualization, and volumetric quantification of high-grade brain glioma (WHO grade 3 astrocytoma, WHO grade 4 astrocytoma and WHO grade 4 glioblastoma) from a set of standard MRI images of male or female patients 18 years of age or older who are known to have pathologically proven high-grade glioma.</p> <p>Volumetric measurements may be compared to past measurements if available. NS-HGlio is not to be used for primary diagnosis, and is intended to be used by qualified clinical personnel as an additional source of information and is not intended to be the sole diagnostic metric.</p>	<p>Cercare Medical Neurosuite (CMN) and associated modules is an image processing software package to be used by trained professionals, including physicians and medical technicians.</p> <p>The CMN software package runs on standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM (Digital Imaging and Communications in Medicine) compliant imaging devices. CMN provides viewing capabilities of datasets acquired with MRI and CT.</p> <p>The Capillary Function module provides analysis capabilities for functional and dynamic imaging datasets acquired with MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT). The Capillary Function module is used for visualization and analysis of dynamic</p>	<p>Same – SD combines indications of both the PD and RD with the exception of the Virtual Expert portion of the RD; No new questions of safety or effectiveness.</p>

Description	Subject Device	Predicate Device (K221738)	Reference Device (K241989)	Conclusion
	<p>functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. In addition, the Capillary Function module's DWI technology is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.</p> <p>Oncology Virtual Expert is intended for semi-automatic labeling, visualization, and volumetric quantification of brain glioma (WHO Grade II through IV), including glioblastoma (WHO Grade IV), astrocytoma (WHO Grade II, III, and IV), and oligodendroglioma (WHO Grade III), from a set of standard MRI images of adult patients who are known to have pathologically proven glioma. Volumetric measurements may be automatically compared to prior measurements when available; to minimize measurement variability, such longitudinal comparisons should be performed using the same scanner model and consistent acquisition parameters. Oncology Virtual Expert is not to be used for primary diagnosis and is intended to be used by trained professionals as an additional source of information for decision support.</p>		<p>imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. In addition, the Capillary Function module's DWI technology is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.</p> <p>The Virtual Expert module allows the calculation of regions of interest and the visual inspection of time attenuation curves. For MRI, one clinical application is to visualize the apparent blood perfusion and diffusion and to calculate ADC threshold volume, Tmax threshold volume, and Mismatch Ratio in the brain tissue affected by acute stroke.</p> <p>For CT, one clinical application is to visualize the apparent blood perfusion and to calculate rCBF threshold volume, Tmax threshold volume, and Mismatch Ratio in the brain tissue affected by acute stroke.</p> <p>Areas of decreased perfusion appear as areas of changed signal intensity:</p> <ul style="list-style-type: none"> • Lower signal intensity for CBF and CBV • Higher signal intensity for TTP, MTT, and Tmax 	
PACS Functionality				

Description	Subject Device	Predicate Device (K221738)	Reference Device (K241989)	Conclusion
Basic PACS Functions	View, process and analyze medical images. Communication of results through service class user protocols.	Same	Same	Same
Computer Platform	Standard off-the-shelf PC workstation / server	Cloud-based platform only	Same	Same as RD; Difference with PD raises no new questions of safety or effectiveness
	Virtual platform such as VMware		Same	
DICOM Compliance	Yes	Yes	Yes	Same
Features				
Image Types	MRI: Acquired using four different MRI sequences either in 2D or 3D using a specified protocol: <ul style="list-style-type: none"> • T1 pre-contrast • T1 post-contrast • T2 (optional) • FLAIR 	MRI: Acquired using four different MRI sequences either in 2D or 3D using a specified protocol: <ul style="list-style-type: none"> • T1 pre-contrast • T1 post-contrast • T2 • FLAIR 	Same	Same
Intended Anatomy	Brain	Brain	Same	Same
Lesion Review	2D and 3D	2D and 3D	Same	Same
Segmentation	Semi-automatic and manual segmentation of brain glioma (WHO Grade II–IV)	Semi-automatic and manual segmentation of high-grade glioma	N/A	Same

Description	Subject Device	Predicate Device (K221738)	Reference Device (K241989)	Conclusion
Quantification	Volumetric measurement of the sub-components of brain glioma (WHO Grade II–IV)	Volumetric measurement of the sub-components of high-grade glioma	N/A	Same
Volumetric Output	<ul style="list-style-type: none"> Provides volumetric measurements of brain glioma (WHO Grade II–IV) and sub-components Includes segmented color overlays of sub-components and reports Automatically compares results to prior scans when available 	<ul style="list-style-type: none"> Provides volumetric measurements of high-grade brain glioma and sub-components Includes segmented color overlays of sub-components and reports Automatically compares results to prior scans when available 	N/A	Same
Other Output	Summary image characteristics of other images within the glioma sub-components	Not available	N/A	Slight difference raises no new questions of safety or effectiveness
Report	Yes	Yes	Yes	Same

Conclusions

The CMN Capillary Function with Oncology Virtual Expert device performs as intended and presents no unacceptable risks to the intended patient population. The non-clinical bench data supports the safety of the device and demonstrates that the CMN Capillary Function with Oncology Virtual Expert device performs as intended. The CMN Capillary Function with Oncology Virtual Expert is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed Predicate Device (K221738) with comparable characteristics to the Reference Device (K241989).