May 18, 2026

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

Re: K253831
Trade/Device Name: CMN Capillary Function with Virtual Expert for MRI, CT and CBCT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 16, 2026
Received: April 16, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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, PhD
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.	K253831

Please provide the device trade name(s).

CMN Capillary Function with Virtual Expert for MRI, CT and CBCT

Please provide your Indications for Use below.

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, CT, and Cone-Beam CT (CBCT).

The Capillary Function module provides analysis capabilities for functional and dynamic imaging datasets acquired with MRI, CT, or CBCT, including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI, CT or CBCT). 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.

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.

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.

Areas of decreased perfusion appear as areas of changed signal intensity:
- Lower signal intensity for CBF and CBV
- Higher signal intensity for TTP, MTT, and Tmax

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)

Cercare Medical

510(K) SUMMARY

510(k) Number: K253831

Date Prepared: April 15, 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

Table 2: Device Information

Trade Name	Cercare Medical Neurosuite (CMN) Capillary Function with Virtual Expert for MRI, CT and CBCT
Common Name	CMN Capillary Function with Virtual Expert
Classification Name	System, Image Processing, Radiological
Regulation	21 CFR 892.2050
Product Code	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology (OHT8)

The CMN Capillary Function with Virtual Expert for MRI, CT and CBCT device is substantially equivalent to the CMN Capillary Function with Virtual Expert for MR and CT Predicate Device (**Table 3**). The Predicate Device has not been subject to a design-related recall.

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
CMN Capillary Function with Virtual Expert for MRI and CT	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. 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), CT (computed tomography), and CBCT (Cone-Beam CT) 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 is a platform that allows for the addition of certain modules for further analysis. Two of these modules are used in this device: Capillary Function and Virtual Expert.

CMN Capillary Function

Capillary Function, when activated in the installed Cercare Medical Neurosuite, provides further functionalities for reading, writing, visualizing and studying medical images.

Capillary Function provides perfusion post-processing technologies, where dynamically acquired perfusion MRI or perfusion CT/CBCT series can be processed to yield information relevant for assessment of the hemodynamic status of a patient.

Capillary Function generates hemodynamic markers, which can be used for management of diseases with possibly compromised hemodynamic function, such as ischemic stroke and tumors.

The generated output maps can be viewed by standard DICOM image viewers. In addition, Capillary Function includes the possibility for post-processing diffusion-weighted imaging (DWI) MRI data. Post-processing of DWI data results in maps reflective of local water diffusion properties. The post-processed DWI-derived maps can be viewed in standard DICOM image viewers. Capillary Function thus works with MRI, CT and CBCT technologies.

CMN Virtual Expert

Virtual Expert, when activated in the installed CMN Capillary Function, provides further functionalities for reading, writing, visualizing, and studying medical images.

Virtual Expert provides automatic delineation of regions of interest (ROI) relevant for stroke patient assessment based on perfusion and diffusion image output generated by the Capillary Function module. Specifically, diffusion MRI images are used to generate threshold masks of perceived core lesions, whereas MRI, CT or CBCT perfusion images are used to generate threshold masks of perceived perfusion restriction. For CT/CBCT perfusion, derived perfusion images are used to generate threshold masks of perceived core lesions. Virtual Expert thus works with MRI, CT and CBCT technologies.

The generated masks can be combined into a mismatch ROI. Volumetric calculations and ratios can be calculated from the computed ROI.

Cercare Medical

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, CT, and Cone-Beam CT (CBCT).

The Capillary Function module provides analysis capabilities for functional and dynamic imaging datasets acquired with MRI, CT or CBCT including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI, CT or CBCT). 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.

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.

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.

Areas of decreased perfusion appear as areas of changed signal intensity:

- Lower signal intensity for CBF and CBV
- Higher signal intensity for TTP, MTT, and Tmax

Technological Characteristics

CMN Capillary Function with Virtual Expert for MRI, CT and CBCT provides the following functions:

- processes DICOM images from multiple sources to provide visualization of changes of tissue perfusion, diffusion and change
- receives DICOM images from external DICOM image providers (modalities (MRI Scanners), PACS and Workstations) and sends DICOM images to external image consumers
- storage of status and results, and references therein, in a searchable database

CMN Capillary Function with Virtual Expert is a DICOM-compliant PACS software that provides comprehensive functionality to transfer, process and display modality specific imaging data. CMN runs on standard off-the-shelf computer and networking hardware and is entirely independent from CT, MRI or PACS platforms. It supports secure VPN networking or encapsulated Secure Shell (SSH) and seamlessly integrates into an existing radiological data network.

The primary users of CMN software are medical imaging professionals who analyze tissue using MRI, CT or CBCT images. The images generated by CMN provide additional diagnostic information, which is derived from the temporal/diffusion/density features of the native MRI image.

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

CMN Capillary Function with Virtual Expert for MR, CT and CBCT is identical to the Predicate CMN Capillary Function with Virtual Expert for MR and CT (K241989) with the exception of the following features:

- CBCT perfusion post-processing
- CBCT-based detection of stroke lesions

The perfusion processing algorithms cleared under K241989 for CT are reused in whole for the processing of CBCT data, since the fundamental physiological principles are the same, only the modality differs. Both modalities are based on tissue and contrast agent absorption of X-rays (attenuation) but the so-called Hounsfield unit scale is not directly applicable in the case of CBCT. This necessitates a few additional pre-processing steps to technically align the data in terms of image intensity and temporal sampling rate to allow processing with the algorithms cleared under K241989.

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 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 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)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2018
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions, September 2022
- Content of Premarket Submissions for Device Software Functions, June 2023

Performance Data

CMN Capillary Function with Virtual Expert for MR, CT and CBCT 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 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 through bench testing including retrospective clinical data.

For the Capillary Function module, a direct paired device comparison was conducted using 96 digitally simulated CBCT perfusion phantoms spanning clinically relevant ranges of motion, noise, and signal strength. Each phantom was processed by both the CBCT Subject Device and the CT Predicate Device, and the resulting parameter maps were compared using three acceptance metrics: multi-scale structural similarity index (MS-SSIM), patch-level bias, and patch-level correlation. The acceptance criteria were met for 10 of 13 parameter–algorithm combinations. Three timing-sensitive parameters (Delay, Tmax, TTP) showed reduced MS-SSIM acceptance rates attributable to the lower temporal sampling rate of CBCT; patch-bias and patch-correlation acceptance remained above acceptance threshold for these parameters.

For the Virtual Expert module, comparison testing of retrospective patient CT perfusion imaging consisted of primary analyses of volumetric and spatial agreement per-patient and per-lesion. Secondary clinical application assessments (high-level context of the devices not associated with clinical claims) were then conducted in terms of image-driven decision to treat analysis through the so-called DEFUSE3 criteria. The Virtual Expert comparison testing was modeled by the comparison testing conducted for the Predicate Device (K241989) and recognizing that direct comparison across different modalities acquired with varying time delay between acquisitions can be governed by several unknown sources of variation – both technical and disease development-wise.

A blinded, multi-reader multi-case (MRMC) clinical study was additionally conducted in which 13 expert neuroradiologists (8 board-certified and 5 with at least one year of neuroradiology experience) independently scored the diagnostic acceptability of CBCT-derived perfusion parameter maps from 35 acute stroke patients. The MRMC analysis confirmed non-inferiority of the CBCT device relative to the CT Predicate Device on the primary diagnostic-confidence endpoint (observed mean difference −0.171, 95% CI: −0.249 to −0.093; non-inferiority margin −0.5). The co-primary territory-agreement analysis showed that inter-modality weighted κ (0.680) is non-inferior to the matched intra-rater delayed MDCT re-read baseline (κ = 0.690; difference +0.019, 95% CI: −0.065, 0.128; p = 0.629).

The primary known limitation of CBCT perfusion is the lower temporal sampling rate inherent to the modality, which reduces MS-SSIM for timing-sensitive parameters. The spatial structure and clinical diagnostic utility of the maps are preserved, as confirmed by the ≥90% patch-bias and patch-correlation acceptance rates and the non-inferior reader scores in the clinical study.

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

Substantial Equivalence

In comparison with the Predicate CMN Capillary Function with Virtual Expert device (K241989), CMN Capillary Function with Virtual Expert (MR, CT & CBCT) has the same intended use and similar indications, technological characteristics and principles of operation as described in the comparison table below.

Table 4: Substantial Equivalence Comparison Table

Description	Subject Device	Predicate Device (K241989)	Conclusion
Product Name	CMN Capillary Function with Virtual Expert MRI, CT & CBCT	CMN Capillary Function with Virtual Expert CT & MRI	
Manufacturer	Cercare Medical A/S	Cercare Medical A/S	
Product Code / Regulation	LLZ / 21CFR 892.2050	LLZ / 21CFR 892.2050	Same
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.	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,	Similar; Subject Device MR & CT capability identical to Predicate Device and CBCT capability is similar to CT. No new questions of safety or effectiveness.

Description	Subject Device	Predicate Device (K241989)	Conclusion
	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, CT, and Cone-Beam CT (CBCT). The Capillary Function module provides analysis capabilities for functional and dynamic imaging datasets acquired with MRI, CT, or CBCT, including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI, CT or CBCT). 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. 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. 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	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 CT and MRI. 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. 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. For CT, one clinical application is to visualize the apparent blood perfusion and to calculate rCBF threshold volume, Tmax	

Description	Subject Device	Predicate Device (K241989)	Conclusion
	brain tissue affected by acute stroke. Areas of decreased perfusion appear as areas of changed signal intensity: • Lower signal intensity for CBF and CBV • Higher signal intensity for TTP, MTT, and Tmax	threshold volume, and Mismatch Ratio in the brain tissue affected by acute stroke. Areas of decreased perfusion appear as areas of changed signal intensity: • Lower signal intensity for CBF and CBV • Higher signal intensity for TTP, MTT, and Tmax	
PACS Functionality			
Basic PACS Functions	View, process and analyze medical images. Communication of results through service class user protocols.	Yes	Same
Computer Platform	Standard off-the-shelf PC workstation / server	Yes	Same
	Virtual platform such as VMware	Yes	Same
DICOM Compliance	Yes	Yes	Same
Functional Overview	CMN is software package that provides for the visualization and study of changes of tissue in digital images captured by CT, CBCT and MRI. CMN provides viewing and quantification.	CMN is software package that provides for the visualization and study of changes of tissue in digital images captured by CT and MRI. CMN provides viewing and quantification.	Same; Subject Device MR & CT capability identical to Predicate Device and CBCT capability similar to CT. No new questions of safety or effectiveness.
Data Acquisition and Data Types	Acquires medical image data from DICOM compliant imaging devices and modalities; including CT, CBCT and MRI	Acquires medical image data from DICOM compliant imaging devices and modalities; including CT and MRI	Similar; Subject Device MR & CT capability identical to Predicate Device and CBCT capability similar to CT. No new questions of safety or effectiveness.
Acquisition and Modalities Features			

Description	Subject Device	Predicate Device (K241989)	Conclusion
MRI	Diffusion Weighted Image (DWI)	Yes	Same as Predicate Device
	Dynamic Analysis tissue flow (perfusion) and tissue blood volume	Yes	
CT	Dynamic Analysis tissue flow (perfusion) and tissue blood volume	Yes	
Computed Parameter Maps			
Diffusion MRI	Isotropic DWI (isoDWI)	Yes	Same as Predicate Device
	ADC	Yes	
	Zero=gradient image (B=0 image)	Yes	
Perfusion MRI	Relative cerebral blood flow (rCBF)	Yes	Same as Predicate Device
	Relative cerebral blood volume (rCBV)	Yes	
	Mean transit time (MTT)	Yes	
	Delay	Yes	
	Capillary transit time heterogeneity (CTH)	Yes	
	Coefficient of variation (COV)	Yes	
	Model-based oxygen extraction fraction (OEF (model-based))	Yes	
	Model-based relative cerebral metabolic rate of oxygen (rCMRO2 (model-based))	Yes	
	Relative extravasation correction (rLeakage)	Yes	
	rCBF-basic	Yes	
	rCBV-basic	Yes	
	MTT-basic	Yes	
	Tmax-basic	Yes	
Perfusion CT	Relative cerebral blood flow (rCBF)	Yes	Same as Predicate Device

Description	Subject Device	Predicate Device (K241989)	Conclusion
	Relative cerebral blood volume (rCBV)	Yes	
	Mean transit time (MTT)	Yes	
	Delay	Yes	
	Capillary transit time heterogeneity (CTH)	Yes	
	Coefficient of variation (COV)	Yes	
	Model-based oxygen extraction fraction (OEF (model-based))	Yes	
	Model-based relative cerebral metabolic rate of oxygen (rCMRO2 (model-based))	Yes	
	Relative extravasation correction (rLeakage)	Yes	
	rCBF-basic	Yes	
	rCBV-basic	Yes	
	MTT-basic	Yes	
	Tmax-basic	Yes	
Perfusion CBCT	Relative cerebral blood flow (rCBF)	No	Similar to Predicate Device CT; Subject Device comparative performance testing demonstrates SE to Predicate Device
	Relative cerebral blood volume (rCBV)	No	
	Mean transit time (MTT)	No	
	Delay	No	
	Capillary transit time heterogeneity (CTH)	No	
	Coefficient of variation (COV)	No	
	Model-based oxygen extraction fraction (OEF (model-based))	No	
	Model-based relative cerebral metabolic rate of oxygen (rCMRO2 (model-based))	No	
	Relative extravasation correction (rLeakage)	No	
	rCBF-basic	No	
	rCBV-basic	No	

Description	Subject Device	Predicate Device (K241989)	Conclusion
	MTT-basic	No	
	Tmax-basic	No	
Measurement Tools			
MR/CT/CBCT Tools	Arterial input function (AIF)	Yes – MR and CT only	Same; Subject Device MR & CT capability identical to Predicate Device and CBCT capability similar to CT. Minor design differences do not raise new questions of safety or effectiveness.
	Time-course	Yes – MR and CT only	
	Brain mask	Yes – MR and CT only	
	Region of interest (ROI) and Volumetry	Yes – MR and CT only	
	Volumetric comparison between 2 ROIs	Yes – MR and CT only	
	Motion correction	Yes – MR and CT only	
	Export parameter maps PACS and DICOM file systems	Yes – MR and CT only	
	Acquire, transmit, process, and store medical images	Yes – MR and CT only	

Conclusions

The CMN Capillary Function with Virtual Expert (MRI, CT & CBCT) device performs as intended and presents no unacceptable risks to the intended patient population. Non-clinical bench testing demonstrated that 10 of 13 perfusion parameter–algorithm combinations meet the acceptance criterion when compared to the Predicate Device; the 3 timing-sensitive parameters showed reduced structural similarity attributable to the lower temporal sampling rate of CBCT, while maintaining acceptable spatial agreement. A blinded MRMC clinical study confirmed non-inferiority of the CBCT device relative to the Predicate Device. Together with software verification and validation, these results demonstrate that CMN Capillary Function with Virtual Expert (MRI, CT & CBCT) is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed Predicate Device (K241989).