Deep Reasoning Ai, Inc.
% Cooper Molloy
Regulatory Consultant
Innolitics, LLC
1101 W. 34th St. Suite 550
Austin, Texas 78705

October 7, 2026

Re: K262134
Trade/Device Name: NeuroDR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 8, 2026
Received: September 8, 2026

Dear Cooper Molloy:

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.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262134

Please provide the device trade name(s).

NeuroDR

Please provide your Indications for Use below.

NeuroDR is an image analysis software for medical imaging DICOM datasets acquired with CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bones, tissue, and venous vessels, providing a 3D and 2D visualization of the arterial neurovascular supplying blood to the brain.

Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformats (CPR) of the left and right internal carotid and vertebral arteries.

NeuroDR is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation and follow-up of any such lesion and treatment planning.

NeuroDR is intended for use on adult patients. The results of NeuroDR are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Table of Contents

1. Contact Information

2. Device Information

3. Predicate Device Information

4. Device Description

5. Intended Use

6. Indications for Use

7. Contraindications

8. Substantial Equivalence Discussion

8.1. Predicate Device Indications for Use

8.2. Indications for Use Equivalence Discussion

8.3. Device Comparison Table

9. Performance Data

9.1. Software Verification and Validation Testing

9.2. Performance Testing Summary

9.2.1. Segmentation Quality Study

9.2.2. Segmentation Accuracy Study

9.3. Clinical Testing

10. Conclusion

1. Contact Information

Parameter	Value
Company Name	Deep Reasoning AI Inc.
Address	1330 Main Street, Unit 4, Sarasota, FL 34236
Phone Number	+1.941.316.0949
Fax Number	N/A
Company Representative	Jeanne Usonis, CFO

Parameter	Value
Email	jeanne@deepreasoningai.com
Official Correspondent	Cooper Molloy, Regulatory Affairs Specialist
Official Correspondent Company Name	Innolitics, LLC
Official Correspondent Email	fda@innolitics.com
Additional Representatives	Ilya Spivakov, Senior Software Engineer II Meritxell Martinez, Senior Regulatory Affairs Specialist Mary Vater, Director of Regulatory Affairs Yujan Shrestha, MD, Partner
Date Summary Prepared	2026-09-02

2. Device Information

Parameter	Value
Trade Name	NeuroDR
Common Name	Automated radiological image processing software
Product Code	QIH
Regulation Number	21 CFR §892.2050
Regulation Name	Medical image management and processing system
Class	Class II
Panel	Radiology

3. Predicate Device Information

Parameter	Value
Predicate Device Name	Rapid Neuro3D

Parameter	Value
Predicate Device K Number	K243350
Product Code	QIH
Regulation Number	21 CFR §892.2050
Class	Class II
Panel	Radiology

4. Device Description

NeuroDR is a fully automated AI/ML-enabled software as a medical device (SaMD) designed to support users such as radiologists and neurovascular specialists in the evaluation, documentation, and treatment planning of head and neck arterial vasculature. The device operates as a background post-processing step with no manual interaction required.

Inputs and Outputs: NeuroDR takes CTA Head and Neck DICOM data as input and produces three types of visualization outputs: maximum intensity projection (MIP) images, volume rendered (VR) images, and curved planar reformat (CPR) views of the arterial neurovasculature. All outputs are returned as DICOM series to a DICOM node for physician review.

NeuroDR processes a 3D CT/CTA volume through the following steps:

1. Automated data ingestion and pre-processing with quality checks;
2. Voxel-wise segmentation using a deep 3D convolutional neural network based on the U-Net architecture to produce segmentation masks that distinguish head and neck arterial vasculature (anterior and posterior circle) and surrounding brain soft tissues;
3. Recombination of segmentation masks with source DICOM images to generate 3D MIP and VR visualizations with anatomical labeling; and
4. Calculation of vessel centerlines from segmentation masks to generate CPR views.

The core AI model is trained on expert-annotated CTA datasets and optimized to accurately delineate vessels, including small intracranial branches. The model maintains robustness across different scanner manufacturers (Siemens, GE, Toshiba/Canon, Philips) and imaging parameters.

NeuroDR can be deployed on-premises or in a cloud hybrid environment with workflow routing automation integrated with CT scanners and DICOM nodes. The device is fully automated with no manual interaction required to generate images, operating as a background, fully automated post-processing step.

5. Intended Use

NeuroDR is an image analysis software for medical imaging DICOM datasets acquired with CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bones, tissue, and venous vessels, providing a 3D and 2D visualization of the arterial neurovascular supplying blood to the brain.

Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformats (CPR) of the left and right internal carotid and vertebral arteries.

NeuroDR is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation and follow-up of any such lesion and treatment planning.

NeuroDR is intended for use on adult patients. The results of NeuroDR are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.

6. Indications for Use

NeuroDR is an image analysis software for medical imaging DICOM datasets acquired with CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bones, tissue, and venous vessels, providing a 3D and 2D visualization of the arterial neurovascular supplying blood to the brain.

Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformats (CPR) of the left and right internal carotid and vertebral arteries.

NeuroDR is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation and follow-up of any such lesion and treatment planning.

NeuroDR is intended for use on adult patients. The results of NeuroDR are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.

7. Contraindications

There are no contraindications for this device. The device is intended to support analysis of inputs that meet the specified imaging and CTA protocol parameters.

Precautions/Exclusions:

Series containing excessive patient motion or metal implants may impact module output quality.

The NeuroDR device will not process series that meet the following module exclusion criteria:

- CTA datasets with:
    - in-plane X and Y FOV <160 mm or >500 mm.
    - Z FOV (cranio-caudal transverse anatomical coverage) <90 mm.
    - in-plane pixel spacing (X & Y resolution) <0.2 mm or >1.0 mm.
    - Z slice spacing of <0.2 mm or >1.5 mm.
    - slice thickness >1.5 mm.

Output quality and performance may be adversely affected if series that meet the following criteria are provided as input to the NeuroDR device:

- Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU)
- Series acquired with cone-beam CT scanners (c-arm CT)
- Series that are non-axial
- Series with a non-supine patient position
- Series acquired at x-ray tube voltage <70 kVp or >150 kVp.

8. Substantial Equivalence Discussion

8.1. Predicate Device Indications for Use

Rapid Neuro3D is an image analysis software for imaging datasets acquired with conventional CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bone, tissue, and venous vessels, providing a 3D and 2D visualization of the neurovasculature supplying arterial blood to the brain.

Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformation (CPR) of the isolated left and right internal carotid and vertebral arteries.

Rapid Neuro3D is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation, and follow-up of any such lesion and treatment planning.

Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.
RN3D is indicated for adults.

Precautions/Exclusions: Series containing excessive patient motion or metal implants may impact module output quality.The RN3D module will not process series that meet the following module exclusion criteria:

- Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU)
- Series acquired w/cone-beam CT scanners (c-arm CT)
- Series that are non-axial
- Series with a non-supine patient position
- Series containing missing or improperly ordered slices (e.g., as a result of manual correction by an imaging technician)
- CTA datasets with:
    - in-plane X and Y FOV < 160mm or > 400mm.
    - Z FOV (cranio-caudal transverse anatomical coverage) < 90 mm.
    - in-plane pixel spacing (X & Y resolution) < 0.2 mm or > 1.0 mm.
    - Z slice spacing of < 0.2 mm or > 1.25 mm.
    - slice thickness > 1.5mm.
    - data acquired at x-ray tube voltage < 70kVp or > 150kVp.

8.2. Indications for Use Equivalence Discussion

The devices have identical indications for use, being used to automatically segment vasculature from CTAs of the aortic arch to the vertex of the head and produce image outputs.

The devices have identical technological characteristics utilizing machine learning to automatically segment vasculature from CTAs of the aortic arch to the vertex of the head and produce image outputs.

The indications for use of the Predicate Device and Subject Device are substantially equivalent.

8.3. Device Comparison Table

Feature/Function	NeuroDR	Rapid Neuro3D (K243350)	Comments
Regulation	21 CFR 892.2050; Medical image management and processing system.	21 CFR 892.2050; Medical image management and processing system.	Same.
Product Code	QIH	QIH	Same.
Device Type	SaMD image processing module for visualization and segmentation of arterial vessels of the head and neck in CTA exams.	SaMD image processing module within the Rapid Platform for visualization and segmentation of arterial vessels of the head and neck in CTA exams.	Same.

Indications for Use	NeuroDR is an image analysis software for medical imaging DICOM datasets acquired with CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bones, tissue, and venous vessels, providing a 3D and 2D visualization of the arterial neurovascular supplying blood to the brain. Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformats (CPR) of the left and right internal carotid and vertebral arteries. NeuroDR is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation and follow-up of any such lesion and treatment planning. NeuroDR is intended for use on adult patients. The results of NeuroDR are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.	Rapid Neuro3D (RN3D) is an image analysis software for imaging datasets acquired with conventional CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bone, tissue, and venous vessels, providing a 3D and 2D visualization of the neurovasculature supplying arterial blood to the brain. Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformation (CPR) of the isolated left and right internal carotid and vertebral arteries. Rapid Neuro3D is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation, and follow-up of any such lesion and treatment planning. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment. RN3D is indicated for adults. Precautions/Exclusions:Series	Both devices are image-analysis software for CTA of the head and neck that remove non-arterial structures and provide 2D and 3D visualizations of the arterial neurovasculature to support the physician in confirming the presence or absence of physician-identified lesions, and in evaluation, documentation, follow-up, and treatment planning. Both are adjunctive tools whose results are not intended to be used on a stand-alone basis for clinical decision-making or to preclude clinical assessment. The precautions/exclusions are not included in the indications for use for NeuroDR, they are instead included in the contraindications and device labeling.

Feature/Function	NeuroDR	Rapid Neuro3D (K243350)	Comments
		containing excessive patient motion or metal implants may impact module output quality.The RN3D module will not process series that meet the following module exclusion criteria: • Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU) • Series acquired w/cone-beam CT scanners (c-arm CT) • Series that are non-axial • Series with a non-supine patient position • Series containing missing or improperly ordered slices (e.g., as a result of manual correction by an imaging technician)CTA datasets with:in-plane X and Y FOV < 160mm or > 400mm.Z FOV (cranio-caudal transverse anatomical coverage) < 90 mm.in-plane pixel spacing (X & Y resolution) < 0.2 mm or > 1.0 mm.Z slice spacing of < 0.2 mm or > 1.25 mm.slice thickness > 1.5mm.data acquired at x-ray tube voltage < 70kVp or > 150kVp.	

Precautions/Exclusions	Series containing excessive patient motion or metal implants may impact module output quality. The NeuroDR device will not process series that meet the following module exclusion criteria: • CTA datasets with: ◦ in-plane X and Y FOV <160 mm or >500 mm. ◦ Z FOV (cranio-caudal transverse anatomical coverage) <90 mm. ◦ in-plane pixel spacing (X & Y resolution) <0.2 mm or >1.0 mm. ◦ Z slice spacing of <0.2 mm or >1.5 mm. ◦ slice thickness >1.5 mm. Output quality and performance may be adversely affected if series that meet the following criteria are provided as input to the NeuroDR device: • Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU) • Series acquired with cone-beam CT scanners (c-arm CT) • Series that are non-axial • Series with a non-supine patient position • Series acquired at x-ray tube	Series containing excessive patient motion or metal implants may impact module output quality. The RN3D module will not process series that meet the following module exclusion criteria: • Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU) • Series acquired w/cone-beam CT scanners (c-arm CT) • Series that are non-axial • Series with a non-supine patient position • Series containing missing or improperly ordered slices (e.g., as a result of manual correction by an imaging technician) • CTA datasets with: ◦ in-plane X and Y FOV < 160mm or > 400mm. ◦ Z FOV (cranio-caudal transverse anatomical coverage) < 90 mm. ◦ in-plane pixel spacing (X & Y resolution) < 0.2 mm or > 1.0 mm. ◦ Z slice spacing of < 0.2 mm or > 1.25 mm. ◦ slice thickness > 1.5mm. ◦ data acquired at x-ray tube voltage < 70kVp or > 150kVp.	Both devices include very similar features and values in the precautions/exclusions. For some of the precautions/exclusions, the NeuroDR device does not reject the input, but it is explicitly stated that NeuroDR is not intended to be used on such inputs.

Feature/Function	NeuroDR	Rapid Neuro3D (K243350)	Comments
	voltage <70 kVp or >150 kVp.		
Intended Users	Radiologists; neurovascular and neurosurgical specialists such as vascular neurosurgeons, neuro-interventional specialists, ED physicians; or users with similar training, such as radiology technologists.	Radiologists, neurovascular and neurosurgical specialists, such as vascular neurosurgeons, neuro-interventional specialists, ED physicians, or users with similar training.	The intended users are very similar. Both devices are intended to support radiologists, neurovascular and neurosurgical specialists, and users with similar training. NeuroDR specifically identifies radiology technologists as users with similar training.
Technological Characteristics	—	—	—
Imaging Modality	CTA	CTA	Same.
Imaging Type	Neurological (aortic arch to the vertex of the head)	Neurological (aortic arch to the vertex of the head)	Same.
Software Outputs	• 2D/3D vessel visualization (MIPS, VR, CPR) • Automated segmentation and removal of obstructive bones and/or vessels	• 2D/3D vessel visualization (Thins, MIPS, VR, CPR) • Automated segmentation and removal of obstructive bones and/or vessels	Same.
Vessel Visualization	Outputs will display the arterial vasculature as well as views separated into anterior circle and posterior circle.	Outputs will display the arterial vasculature.	Both devices provide view of the arterial vasculature, but the subject device also provides outputs that separate the vasculature into the anterior circle and posterior circle for ease of viewing.

Feature/Function	NeuroDR	Rapid Neuro3D (K243350)	Comments
Functionality / Workflow	"Headless" AI/ML- enabled SaMD. Provides outputs as secondary capture.	Software package (SaMD) which interfaces to a PACS/Viewer or allows viewing within the application.	Both devices are SaMD post-processing modules that receive CTA DICOM studies from existing imaging infrastructure, automatically process the images, and return secondary-capture/DICOM outputs for review on standard PACS or compatible viewers. NeuroDR operates as a "headless" background module while Rapid Neuro3D may also allow viewing within the application; these implementation differences do not alter the clinical workflow, user interaction with the images, or raise new questions of safety or effectiveness.
Computer Platform	Standard off-the-shelf Hardware: On Premises or Cloud Hybrid	Standard off-the-shelf Hardware: On Premises or Cloud Hybrid	Same.
Technical Implementation	AI/ML	AI/ML	Same.

9. Performance Data

9.1. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by 2023 FDA Guidance “Content of Premarket Submissions for Device Software Functions”.

The software verification and validation testing verified that the design requirements were successfully met. The Intended use and user needs were successfully validated.

As the intended use, functionality and performance of the subject device and the predicate device are equivalent, the result of the performance testing is evidence that the NeuroDR performs in an equivalent manner to the Rapid Neuro3D.

9.2. Performance Testing Summary

NeuroDR conducted standalone performance validation testing (segmentation quality and segmentation accuracy). DICOM volumes from all major CT scanner manufacturers (GE, Philips, Siemens, and Toshiba/Canon) collected using various scanning parameters (kVp, Exposure, slice thickness, convolution kernel) were included in the test datasets. The test datasets included representative distributions of age/sex/geographic location and incorporated data with potential confounders (such as abnormalities, anomalies, and pathologies) to assess the impact on device performance. The test datasets were independent from the data used during model training.

9.2.1. Segmentation Quality Study

The segmentation quality study used 120 CTA cases from 120 patients (65 Female, 55 Male; aged 16 to 100) to compare the outputs of NeuroDR to the raw DICOM images. Each image output type was evaluated: volume renderings (VRs), maximum intensity projections (MIPs), and curved planar reformats (CPRs). For each image, 3 VR outputs (anterior, posterior, both), 3 MIP outputs (anterior, posterior, both), and 4 CPR outputs (left carotid, right carotid, left vertebral, right vertebral) were produced by the device.

The primary endpoint, clinical accuracy, was determined by up to 3 clinical experts against the source DICOM images via rating on a 5 point Likert scale (1-5). These acceptance criteria were met by each NeuroDR output type. The following table illustrates the performance of each output type.

Metric	Observed Result
3D VR Anterior	4.73

Metric	Observed Result
3D VR Posterior	4.78
3D VR Full	4.66
MIP Anterior	4.70
MIP Posterior	4.78
MIP Full	4.65
CPR Left Carotid	4.89
CPR Right Carotid	4.90
CPR Left Vertebral	4.93
CPR Right Vertebral	4.90

The secondary endpoint, labeling, was met with 100% accuracy (anterior and posterior vasculature, left/right carotid and left/right vertebral were all determined to be accurate).

9.2.2. Segmentation Accuracy Study

The segmentation accuracy study used 50 CTA cases from 50 patients (26 Female, 24 Male; aged 22 to 93) to assess the performance of NeuroDR compared to expert-annotated ground truth. The segmentation accuracy study was split by anatomical region, anterior and posterior vasculature. Some vasculature elements are considered to be included in both the anterior and posterior vasculature.

For the anterior segment of the segmentation accuracy study, the primary endpoint was achieved with an average DICE score of 0.95 and average Hausdorff Distance of 0.40 mm across all cases.

For the posterior segment of the segmentation accuracy study, the primary endpoint was achieved with an average DICE score of 0.96 and average Hausdorff Distance of 0.13 mm across all cases.

The primary endpoint of CPR visualizations was achieved with an average Hausdorff Distance of 0.45 mm for anterior centerlines and 0.41 for posterior centerlines.

9.3. Clinical Testing

No clinical testing was necessary to validate the subject device.

10. Conclusion

NeuroDR shares similar technological characteristics, intended use, and functionality with Rapid Neuro3D. There are no differences between the devices that raise new questions of safety and effectiveness.

Furthermore, non-clinical performance test data and software verification and validation demonstrate that NeuroDR performs comparably to the predicate device in terms of safety and effectiveness.

Based on the device comparisons and the acceptable testing results, it is determined that NeuroDR is substantially equivalent to the predicate device.