NICo-Lab B.V.
℅ Veronica Padharia
Principal Regulatory Affairs Specialist
Paascheuvelweg 25
Amsterdam, 1105BP
Netherlands

December 14, 2023

Re: K231570
Trade/Device Name: StrokeViewer Perfusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 21, 2023
Received: November 21, 2023

Dear Veronica Padharia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231570

Device Name
StrokeViewer Perfusion

Indications for Use *(Describe)*
StrokeViewer Perfusion is an image processing software package intended to provide quantitative perfusion information in brain tissue for suspected ischemic stroke patients. It is to be used by medical imaging professionals who analyze dynamic perfusion studies, including but not limited to physicians such as neurologists, and radiologists.

The software is packed as a Docker container allowing installation on a standard "off-the-shelf" computer or a virtual platform. The software can be used to perform image viewing, processing, and analysis of brain CT perfusion (CTP) images. Data and images are acquired through DICOM compliant imaging devices.

StrokeViewer Perfusion is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time, which are visualized as colored perfusion maps including flow-related parameters and tissue blood volume quantification.

Contraindications:
- Bolus Quality: absent or inadequate bolus.
- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate
- Presence of hemorrhage

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K231570

510(k) Summary StrokeViewer Perfusion

[As required by section 21 CFR 807.92(c)]

NIC-230142-06-F

13-Dec-2023

Nicolab
Paasheuvelweg 25
1105 BP Amsterdam
The Netherlands

Contents

Nicolab
Paasheuvelweg 25
1105 BP Amsterdam
The Netherlands

1 Identification of the Submitter

Importer/Distributor	NICo-Lab B.V. (Nicolab)	
Establishment Registration Number	3021915828	
Submitter Contact Information	Primary Contact	Secondary Contact
Name	Veronica Padharia	Jorrit Boersen
Title	Principal RA Specialist	RA Specialist
E-mail	vpadharia@nicolab.com	jboersen@nicolab.com
Phone Number	630-917-1160	+31(0)6 341 88 966

2 Device Name and Classification

	Subject Device	Predicate Device (K182130)	Reference Device (K200873)
Device Name	StrokeViewer Perfusion	iSchemaView Rapid	StrokeViewer HALO
Proprietary Trade Name	StrokeViewer Perfusion	Rapid	HALO (LVO Triaging)
Product Classification	LLZ	LLZ	QAS
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Radiological Computer Aided Triage and Notification Software
Classification Panel	Radiology	Radiology	Radiology
CFR Section	21 CFR §892.2050	21 CFR §892.2050	21 CFR §892.2080
Device Class	Class II	Class II	Class II

3 Device Description

StrokeViewer Perfusion is an image processing application that runs on a standard "off-the-shelf" computer or a virtual platform, and can be used to perform image processing and analysis of CT perfusion images of the brain.

The software can receive, identify and extract DICOM information embedded in the imaging data. The output includes parametric maps related to tissue blood flow (perfusion) and tissue blood volume. Results of the analysis are exported as DICOM series and DICOM reports and can be sent to a preconfigured destination and can be reviewed on a compatible DICOM viewer. StrokeViewer Perfusion image analysis includes calculation of the following perfusion related parameters:

- Cerebral Blood Flow (CBF)
- Cerebral Blood Volume (CBV)
- Mean Transit Time (MTT)
- Residue function time-to-peak (TMax)
- Arterial Input Function (AIF)
- Volume calculations of affected tissue based on Tmax and CBF abnormalities

The device description and overall fundamental scientific technology of the StrokeViewer Perfusion algorithm is equivalent to the predicate device (K182130) in addition to the listed reference devices within this submission.

4 Intended Purpose

StrokeViewer Perfusion is an image processing software application that analyzes CT scans of the brain to provide quantitative perfusion information in brain tissue for suspected ischemic stroke patients. Additionally, it performs calculations to quantify areas of perfusion in the brain.

StrokeViewer provides this information to the user to include it as additional data to interpret and analyze CTP scans of suspected stroke patients for the adult population. There is no change to the standard of care assessment of suspected stroke patients where the healthcare professional assesses the medical images. StrokeViewer only provides additional imaging data and numerical data that may be taken into consideration by a healthcare professional. StrokeViewer is not intended to be used as a standalone diagnostic tool, and StrokeViewer output should always be interpreted in the context of clinical information about the patient rather than in isolation.

4.1 Indications for Use

StrokeViewer Perfusion is an image processing software package intended to provide quantitative perfusion information in brain tissue for suspected ischemic stroke patients. It is to be used by medical imaging professionals who analyze dynamic perfusion studies, including but not limited to physicians such as neurologists, and radiologists.

The software is packed as a Docker container allowing installation on a standard "off-the-shelf" computer or a virtual platform. The software can be used to perform image viewing, processing, and analysis of brain CT perfusion images (CTP) images. Data and images are acquired through DICOM compliant imaging devices.

StrokeViewer Perfusion is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time, which are visualized as colored perfusion maps including flow-related parameters and tissue blood volume quantification.

Contraindications:

- Bolus Quality: absent or inadequate bolus.
- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
- Presence of hemorrhage

5 Comparison of Indications for Use Statements

Comparison of the indications for use statements between the subject and predicate cleared devices show that the statements are similar in classification of device, intended users, types of platform environments as well as the types of data required for input in order to acquire the identical types of output parameters for CT Perfusion.

The only difference between the devices is that StrokeViewer Perfusion currently does not support CTA or MR data in analysis of the Perfusion algorithm. StrokeViewer Perfusion's indications for use statement is considered to be a subset of the indications for use that the predicate cleared device utilizes.

Given this difference, we have concluded that the differences in fundamental scientific technology do not affect the existing features of the StrokeViewer platform, the introduction of the StrokeViewer Perfusion algorithm to our existing platform, nor does it raise different questions of the safety and effectiveness of the StrokeViewer device, including the Perfusion algorithm.

6 Comparison of Technological Characteristics with the Predicate Device

As compared to the predicate device (K182130), StrokeViewer Perfusion works with Computed Tomography (CT) DICOM compliant medical image data. The algorithm analyzes dynamic imaging data acquired using CT perfusion scan protocol.

StrokeViewer Perfusion also similarly provides tools for performing the following types of analysis as compared to the predicate device:

- Volumetry of threshold maps
- Time-intensity plots for dynamic time courses
- Measurement of mismatch between labeled volumes on co-registered image volumes

Like the predicate device, the StrokeViewer software consists of a variety of modules which support different analysis methods used in clinical practice. For this submission, the following is available with the introduction of the Perfusion algorithm:

- StrokeViewer Dynamic Analysis: used to visualize and analyze dynamic imaging data that displays properties of changes in contrast over time. This includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume: CBF, CBV, MTT and Tmax.

The main difference between StrokeViewer Perfusion and the predicate cleared device, iSchemaView Rapid (K182130), is that StrokeViewer Perfusion does not analyze CTA or MR data.

The platform previously cleared as part of the reference device, StrokeViewer HALO (LVO Triaging, K200873), is now able to accommodate the deployment of the Perfusion algorithm. The previously cleared features remain unchanged. This addition/feature is optional.

StrokeViewer Perfusion's indications for use statement is considered to be similar to that of the predicate device. The minor differences in fundamental scientific technology do not affect the existing features of the StrokeViewer platform, the introduction of the StrokeViewer Perfusion algorithm to our existing platform, nor does it raise different questions of the safety and effectiveness of StrokeViewer Perfusion.

7 Performance and safety

7.1 Software Validation and Verification

Performance data has been provided in this submission in accordance to the following FDA Guidance Documents in order to support our conclusion of substantial equivalence to the predicate device:

- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices—Final Guidance", October 2, 2014
- "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices", September 6, 2017

The performance data included is in accordance with the general controls outlined for a Software as a Medical Device (SaMD).

Design, risk management, verification, and validation were carried out in compliance with CFR 21 Part 820 and the DICOM standard (NEMA PS 3.1-3.20). The results of software verification, validation, and algorithmic testing demonstrate that StrokeViewer Perfusion meets all design requirements and specifications for its intended use.

The testing included within this submission upholds our statement for safety and effectiveness of the proposed device while supporting our claim of substantial equivalence to the predicate device, K182130.

7.2 Performance testing

Clinical data was not required for this submission of the StrokeViewer Perfusion. We believe the safety and effectiveness of the proposed device was appropriately tested with non-clinical validation.

Software testing data included in the submission is in accordance with controls outlined for Software as a Medical Device and comprises the following testing: Unit testing, End-to-end testing, and reproducibility testing.

Non-clinical bench performance testing was performed to assess Perfusion algorithm performance on simulated datasets (Kudo digital phantom) generated using simulating tracer kinetic theory. Correlations between the output of the StrokeViewer Perfusion device and the ground truth values were calculated. The results of algorithm performance testing showed that the device met performance goals and acceptance criteria.

The tests performed demonstrate that Perfusion in StrokeViewer performs as intended. All testing included within the respective sections of this submission uphold our belief that StrokeViewer is substantially equivalent to the predicate device (K182130).

7.3 Risk Management File

StrokeViewer Perfusion was tested according to the FDA guidance and recognized standards. ISO 14971:2019, Medical devices—Application of risk management to medical devices, was followed.

All risk controls were identified, implemented, and mitigated according to hazards identified. All testing related to risk controls support the acceptance criteria outlined for our software requirement specifications.

7.4 Recognized Consensus Standards

FDA Recognized Consensus Standards were followed when testing the Perfusion feature within StrokeViewer to uphold claims of safety and effectiveness of the intended purpose of the device:

Date of Entry	Recognition Number	Standards Developing Organization	Standard Designation Number and Date	Title of Standard
12/23/2019	5-125	ISO	14971:2019	Medical devices – Applications of risk management to medical devices
07/06/2020	5-129	IEC	62366-1:2015+AMD1:2020 (Consolidated text)	Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
01/14/2019	13-79	IEC	62304:2006/A1:2016	Medical device software – Software lifecycle processes (including Amendment 1 (2016))
12-19-2022	12-349	NEMA	PS 3.1 – 3.20 2022d	Digital Imaging and Communications in Medicine (DICOM) Set

12/20/2021	5-134	ISO	15223-1 Fourth edition 2021-07	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
12/19/2022	5-135	ISO	20417 First edition 2021-04 Corrected version 2021-12	Medical devices – Information to be supplied by the manufacturer
08/21/2017	13-97	IEC	82304-1 Edition 1.0 2016-10	Health Software – Part 1: General requirements for product safety

Harmonized standards that are not declared in the FDA Recognized Standards Database but are still followed:

Standard Designation Number	Title of Standard
ISO 13485:2016	Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes
ISO/IEC 27001:2022	Information Security, Cybersecurity and privacy protection—Information security management systems—Requirements
NEN 7510-1:2017+A1:2020	Health informatics—Information security management in healthcare—Part 1: Management System
NEN 7510-2:2017	Health informatics—Information security management in healthcare—Part 2: Controls

8 Conclusion

StrokeViewer Perfusion's indications for use are similar to the predicate device (K182130).

The fundamental technological characteristics between both devices are similar as well. All attributes of the tested software, when compared, uphold our claim of substantial equivalence.

Nicolab considers StrokeViewer Perfusion to demonstrate the same safety and efficacy to the commercially available predicate device. Therefore, we believe StrokeViewer Perfusion demonstrates substantial equivalence to the predicate device (K182130) and have included evidence to support this statement throughout the submission.

Nicolab
Paasheuvelweg 25
1105 BP Amsterdam
The Netherlands