NiCo-Lab B.V.   November 20, 2020
℅ Roujuan Zhang
Consultant
MD Squared B.V.
High Tech Campus 29
Eindhoven, 5858AE
NETHERLANDS

Re: K200873
    Trade/Device Name: HALO
    Regulation Number: 21 CFR 892.2080
    Regulation Name: Radiological computer aided triage and notification software
    Regulatory Class: Class II
    Product Code: QAS
    Dated: October 1, 2020
    Received: October 5, 2020

Dear Roujuan Zhang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
    and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K200873

Device Name
HALO

Indications for Use *(Describe)*

HALO is a notification only cloud-based image processing software application using artificial intelligence algorithms to analyze patient imaging data in parallel to the standard of care imaging interpretation. Its intended use is to identify suggestive imaging patterns of a pre-specified clinical condition and to directly notify an appropriate medical specialist.

HALO's indication is to facilitate the evaluation of the brain vasculature on patients suspected of stroke by processing and analyzing contrast enhanced CT angiograms of the brain acquired in an acute setting. After completion of the data analysis, HALO sends a notification if a pattern suggestive for a suspected intracranial Large Vessel Occlusion (LVO) of the anterior circulation (ICA, M1 or M2) has been identified in an image.

The intended users of HALO are defined as appropriate medical specialists or a team of specialists that are involved in the diagnosis and care of stroke patients at emergency departments or other department where stroke patients are administered. They include physicians such as neurologists, radiologists, and/or other emergency department physicians.

HALO's output should not be used for primary diagnosis or clinical decisions; the final diagnosis is always decided upon by the medical specialist. HALO is indicated for CT scanners from GE Healthcare.

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.

510(k) Summary

Date Prepared:	March 27, 2020	
Manufacturer:	NICo-Lab B.V. Paasheuvelweg 25, 1105BP, Amsterdam The Netherlands	
Contact Person:	Merel Boers CEO Phone: +31202440852 E-mail: mboers@nico-lab.com	
Device:	Trade Name:	HALO
	Classification Name:	Radiological Computer-Assissted Triage and Notification Software
	Classification Regulation:	21 CFR 892.2080
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	QAS
Primary Predicate Device:	Trade Name:	ContaCT
	Manufacturer:	Viz.Al, Inc.
	DeNovo Clearance:	DEN170073
	Classification Name:	Radiological Computer-Assissted Triage and Notification Software
	Classification Regulation:	21 CFR 892.2080
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	QAS

Device description:

HALO is a notification only, cloud-based clinical support tool which identifies image features and communicates the analysis results to a specialist in parallel to the standard of care workflow.

HALO is designed to process CT angiograms of the brain and facilitate evaluation of these images using artificial intelligence to detect patterns suggestive of an intracranial large vessel occlusion (LVO) of the anterior circulation.

A copy of the original CTA images is sent to HALO cloud servers for automatic image processing. After analyzing the images, HALO sends a notification regarding a suspected finding to a specialist, recommending review of these images. The specialist can review the results remotely in a compatible DICOM web viewer.

Indications for Use: HALO is a notification only cloud-based image processing software application using artificial intelligence algorithms to analyze patient imaging data in parallel to the standard of care imaging interpretation. Its intended use is to identify suggestive imaging patterns of a pre-specified clinical condition and to directly notify an appropriate medical specialist.

HALO's indication is to facilitate the evaluation of the brain vasculature on patients suspected of stroke by processing and analyzing CT angiograms of the brain acquired in an acute setting. After completion of the data analysis, HALO sends a notification if a pattern suggestive for a suspected intracranial Large Vessel Occlusion (LVO) of the anterior circulation (ICA, M1 or M2) has been identified in an image.

The intended users of HALO are defined as medical specialists or a team of specialists that are involved in the diagnosis and care of stroke patients at emergency departments or other department where stroke patients are administered. They include physicians such as neurologists, radiologists, and/or other emergency department physicians.

HALO's output should not be used for primary diagnosis or clinical decisions; the final diagnosis is always decided upon by the medical specialist. HALO is indicated for CT scanners from GE Healthcare.

Technological characteristics:

Both HALO and the predicate device *ContaCT* are intended as a notification-only, parallel workflow tool to identify and communicate

images of specific patients to a specialist, independent of standard of care workflow. After completion of the data analysis, both devices send a notification if a pattern suggestive for a suspected Large Vessel Occlusion (LVO) has been identified in the dataset.

The technological characteristic of HALO and how it is comparable to the currently marketed and predicate device *ContaCT* are summarized below.

	Predicate: ContaCT	**Subject: HALO**
Clinical condition	Large vessel occlusion	Large vessel occlusion
Anatomical region of interest	Head	Head
Data acquisition protocol	CT angiogram images of the brain	CT angiogram images of the brain
Segmentation of region of interest	No; device does not mark, highlight, or direct users' attention to a specific location in the original image.	No; device does not mark, highlight, or direct users' attention to a specific location in the original image.
Core Algorithm	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images
Device Output/ Notification	The software sends a notification to the specialist identifying the study of interest. Additionally, the device also provides a DICOM viewing mobile application allow users preview the images.	The software sends a notification email to the specialist identifying the study of interest. Additionally, the device provides user with a link to DICOM Web viewer allowing users review the images.
Triage effectiveness	Notification time is defined as the time from CTA to notification.	Notification time is defined as the time from CTA to notification.
Independent of standard of care workflow	No cases are removed from worklist	No cases are removed from worklist

Based on the information provided above, non-clinical and clinical performance tests provided in this 510(k) premarket notification demonstrate the proposed HALO is considered substantially equivalent to

its predicate device *ContaCT* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-Clinical software testing has been performed in accordance with the "*Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (issued May 11, 2005, document number 337) and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (issued October 2, 2014, document number 1825)**.**

All these tests were used to support substantial equivalence of the subject device and demonstrate that the performance of HALO is according to predefined user requirements, system level requirements and the risk control measures. The device meets the acceptance criteria and is adequate for its intended use.

Summary of Clinical Performance Data:

In a multi-center clinical study, the performance of the HALO clinical decision support algorithm for LVO detection was retrospectively evaluated in a consecutive patient cohort admitted to US comprehensive stroke centers.

Three hundred forty-eight CTA scans of the brain were collected. After exclusion, 364 patients were included for further analyses. Ground truth was established by an expert panel consisting of 3 neuro radiologists.

For the primary endpoint: calculation of the performance of the HALO algorithm showed a sensitivity and specificity for LVO detection of respectively 91.1% (95% CI, 86.0%-94.8%) and 87.0% (95% CI, 81.2%-91.5%). The area under the curve (AUC) is 0.97.

For the secondary endpoints the median notification time for the detected LVO cases was 4 minutes 31 seconds, with a minimum of 3:47 and maximal 7:12.

The HALO performance with regard to sensitivity and specificity, and the notification time are both equivalent to that of the selected predicate device: *ContaCT* of Viz.AI.

Therefore, the HALO algorithm fulfills the requirement of a suitable screening tool to support diagnosis of LVOs by flagging these scans as requiring urgent radiologist review.

Substantial Equivalence Conclusion: The non-clinical and clinical performance tests provided in this 510(k) premarket notification demonstrate HALO is substantially equivalence to the currently marketed predicate device *ContaCT* (DEN 170073) in terms of indications for use, technological characteristics and safety and effectiveness. The differences between the subject device and predicate device do not alter the triage use of the device and do not affect its safety and effectiveness.