



Nico.Lab B.V.
% Ruojuan Zhang
RA Consultant
MD Squared B.V.
High Tech Campus 29
Eindhoven, Noord Brabant 5656 AE
THE NETHERLANDS

July 8, 2021

Re: K211788
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: June 5, 2021
Received: June 9, 2021

Dear Ruojuan 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)

K211788

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 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 and Philips.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Submission Number: K211788

Date Prepared: June 4, 2021

Manufacturer: NICO.LAB B.V.
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Device:

| | |
|----------------------------|---|
| Trade Name: | HALO |
| Classification Name: | Radiological Computer-Assisted Triage and Notification Software |
| Classification Regulation: | 21CFR §892.2080 |
| Classification Panel: | Radiology |
| Device Class: | Class II |
| Primary Product Code: | QAS |

Primary Predicate Device:

| | |
|----------------------------|---|
| Trade Name: | HALO |
| Manufacturer: | NICO.LAB B.V. |
| 510(k) Clearance: | K200873 (November 20, 2020) |
| Classification Name: | Radiological Computer-Assisted Triage and Notification Software |
| Classification Regulation: | 21CFR §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 departments 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 and Philips.

Technological characteristics: The subject device, HALO, is substantially equivalent to the predicate device, the previously cleared version of the HALO (K200873). In comparing the technological characteristics, both the subject and predicate devices 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. After analyzing the images, the device sends a notification regarding a suspected finding to a specialist, recommending review of these images. Where the subject and predicate only differ is that the subject device not only process images from GE Healthcare, but also Philips scanners.

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

| | Predicate | Subject |
|---|---|---|
| | HALO | 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 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. | 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 between upload of CTA (CTA images are received in the cloud) to the availability of AI results (user receives a notification to view | Notification time is defined as the time between upload of CTA (CTA images are received in the cloud) to the availability of AI results (user receives a notification to view |

| | | |
|---|------------------------------------|------------------------------------|
| | the suspected finding). | the suspected finding). |
| Independent of standard of care workflow | No cases are removed from worklist | No cases are removed from worklist |

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.

434 CTA scans of the brain were collected. After exclusion, 427 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 91.3% (95% CI, 86.6%-94.8%) and 85.9% (95% CI, 80.6%-90.2%). 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 29 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. Therefore, the HALO algorithm fulfils 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 clinical performance tests provided in this 510(k) premarket notification demonstrate HALO is substantial equivalence to its predicate device, the previously cleared HALO (K200873). HALO has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the triage use of the device and do not affect its safety and effectiveness.