CuraCloud Corp.
℅ Yarmela Pavlovic
Regulatory Counsel
Manatt, Phelps & Phillips, LLP
One Embarcadero Center
30th Floor
SAN FRANCISCO CA 94111

April 13, 2020

Re: K192167
Trade/Device Name: CuraRad-ICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: March 24, 2020
Received: March 24, 2020

Dear Yarmela Pavlovic:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K192167

Device Name

CuraRad-ICH

Indications for Use *(Describe)*

CuraRad-ICH is a software workflow tool designed to aid in prioritizing the clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage. CuraRad-ICH analyzes cases using deep learning algorithms to identify suspected ICH findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage.

CuraRad-ICH is not intended to direct attention to specific portions of an image or to anomalies other than acute ICH. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out hemorrhage or otherwise preclude clinical assessment of CT studies.

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

CuraCloud's CuraRad-ICH

K192167

Submitter

CuraCloud Corp.
999 Third Ave, Suite 700
Seattle, WA 98104

Phone: (206) 508-1036
Contact Person: Xiaoxiao Liu, Ph.D.

Date Prepared: April 3, 2020

Name of Device: CuraRad-ICH
Classification Name: Radiological Computer-Assisted Triage and Notification Software
Regulatory Class: Class II
Product Code: QAS
Predicate Device: MaxQ-AI Ltd. Accipolx (K182177).

Device Description

CuraRad-ICH is software as a medical device (SaMD) that detects intracranial hemorrhage (ICH) condition by analyzing non-contrast CT images. The software needs to be integrated with a third-party worklist application to receive analysis requests and the corresponding DICOM images, and return the ICH findings (whether suspected ICH is found) to the worklist to alert the radiologists.

For ICH patients, immediate emergency diagnosis and treatment is critical for saving their lives and later recovery. Thus, it is very important to triage and identify ICH patients in a speedy manner in order to prioritize their treatment. Computed tomography (CT) is a non-invasive and effective diagnosis imaging approach to detect ICH. Acute Intracranial hemorrhage can be recognized on non-contrast CT scans since blood has higher density (Hounsfield unit, HU) than other brain tissues but lower than that of bones. Radiologists are able to identify ICH and determine the location and severity of any such bleeding from the intensity patterns presented in the images.

To help radiologists triage and prioritize reading of images for patients with ICH, CuraRad-ICH uses deep learning methods to automatically detect acute ICH in non-contrast head CT scans. The software analyzes the input image and returns a binary prediction as to whether the exam suggests the presence of acute ICH.

Intended Use / Indications for Use

CuraRad-ICH is a software workflow tool designed to aid in prioritizing the clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage. CuraRad-ICH analyzes cases using deep learning algorithms to

identify suspected ICH findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage.

CuraRad-ICH is not intended to direct attention to specific portions of an image or to anomalies other than acute ICH. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out hemorrhage or otherwise preclude clinical assessment of CT studies.

Summary of Technological Characteristics

The core technology of this software is a deep learning algorithm trained on non-contrast head CT scans with ICH ground truth provided by experienced radiologists. The algorithm utilizes an end-to-end trainable 3D classification framework for automatic ICH detection.

The predicate device and the subject device both use deep learning algorithms to detect a pre-defined clinical condition of the brain. Both devices analyze head CT scans immediately after the patient is scanned and works in parallel to and in conjunction with the standard of care workflow. Both devices use the results of its respective detection algorithm to automatically triage and enable prioritization of CT scans for radiologist review, thereby creating an opportunity for earlier diagnosis and treatment of ICH. Although the algorithms differ between the two devices, this difference does not raise any new questions of safety or effectiveness as the core question remains the accuracy of the respective algorithms in detecting ICH.

In addition, both devices are PACS agnostic and can work with any PACS and RIS system. Both devices also flag the suspected ICH on the DICOM images for the radiologist to review.

	CuraRad-ICH	**AccipioIx**
Manufacturer	CuraCloud Corporation	MaxQ AI
Intended Clinical End User	Radiologists/Trained Clinicians	Radiologists/Trained Clinicians
Clinical Condition	Acute Intracranial hemorrhage	Acute Intracranial hemorrhage
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist
AI Used	Yes	Yes
Input Image Modality	Non-contrast Head CT	Non-contrast Head CT
Non-Diagnostic Preview	No	No
Output	Suspected ICH (Yes or No)	Suspected ICH (Yes or No)
Results Receiver	PACS/Workstation	PACS/Workstation

Performance Data

CuraCloud conducted a retrospective, blinded, multisite clinical validation study with CuraRad-ICH. The primary endpoint evaluates the performance of the software in identifying ICH findings from non-contrast head CT scans on a validation dataset of 388 CT studies (213 positives and 175 negatives) from 296 imaging facilities across 48 states in the US.

The observed ICH detection sensitivity was 90.6% (95% CI: 85.9%–94.2%), and specificity was 93.1% (95% CI: 88.3%–96.4%), demonstrating that CuraRad-ICH yielded clinical meaningful results and met the pre-specified criteria for study success on the clinical validation dataset.

The Positive Predictive Value (PPV) and negative predictive value (NPV) of CuraRad ICH were also evaluated. Given that ICH prevalence is not well established and may vary from site to site, analysis was conducted using both low (1%) and high (15%) estimated clinical prevalence, as well as the actual prevalence from the retrospective study. At a prevalence rate of 1%, PPV was 11.8% (95% CI: 7.2%-18.8%) and NPV was 99.9% (95% CI: 99.8%-100%). At a prevalence rate of 15%, PPV was 70% (95% CI: 57.4%-80.1%) and NPV was 98.3% (95% CI: 97.4%-98.8%). At a prevalence rate of 54.9%, PPV was 89.1% (95% CI: 84.3%-92.5%) and NPV was 91.8% (88.6%-94.3%). The NPV was very high across all estimated prevalence rates and, as expected, PPV varied significantly, but was reasonable across prevalence estimates given the relative expected rarity of the condition.

In accordance with FDA's recommendations, stratified analyses were also performed by slice thickness, the number of detector rows and scanner manufacturers. Examining slice thickness up to and including 4.0 mm versus slice thickness greater than 4.0 mm, ICH detection sensitivity was 92.2% and 89.1% respectively, while specificity was 98.7% and 93% respectively. No significant statistical difference was observed between the performance of the two slice thickness groups. Evaluating performance by detector rows also did not produce any statistically notable differences, with sensitivity ranging from 88.4% to 92.9% and specificity ranging from 89.8% to 97.4%. Additionally, no statistically significant differences were revealed when analyzing performance by imaging equipment manufacturer.

The secondary endpoint evaluates the system processing time of the device based on the same validation dataset. The observed system processing time per study is 43 seconds (95%CI: 39~46) in average, with a median time of 33 seconds and a standard deviation of 32 seconds. The minimum observed system processing time was 16 seconds, and the maximum observed processing time was 301 seconds.

Based on the clinical performance as documented in the pivotal clinical study, CuraRad-ICH has a safety and effectiveness profile that is similar to the predicate device.

Conclusions

CuraRad-ICH is as safe and effective as the MaxQ's Accipiolx. CuraRad-ICH has the same intended uses and indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between CuraRad-ICH and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that CuraRad-ICH is as safe and effective as the predicate. Thus, CuraRad-ICH is substantially equivalent.