



MaxQ-AI Ltd.
% Joshua Schulman, Ph.D.
Vice President, Clinical, Regulatory and Quality Affairs
76 Yigal Alon Street, 5th Floor
Tel Aviv, 6706701
ISRAEL

October 26, 2018

Re: K182177
Trade/Device Name: Accipiolx
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: II
Product Code: QAS
Dated: October 4, 2018
Received: October 4, 2018

Dear Dr. Schulman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'hara -S
Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300226759, cn=Michael D. O'hara -S
Date: 2018.10.26 08:54:29 -04'00'

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182177

Device Name

Accipiolx

Indications for Use (Describe)

Accipiolx 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 in the acute care environment. Accipiolx analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage.

Accipiolx is not intended to direct attention to specific portions of an image or to anomalies other than acute intracranial hemorrhage. 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 cases.

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

MaxQ-AI's Accipiolx

Submitter

MaxQ-AI Ltd.
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Tel: +1 -617-765-0333
Contact Person: Joshua Schulman, Ph.D.
Date Prepared: October 4, 2018

Name of Device: Accipiolx

Common or Usual Name/ Classification Name:

Radiological Computer Aided Triage and Notification Software

Regulatory Class: Class II

Regulatory Classification and Product Code: 21 C.F.R. § 892.2080; QAS

Predicate Device: ContaCT (Viz.AI), DEN170073

Reference Device: AiDoc Briefcase (K180647)

Device Description

Accipiolx is a software device designed to be installed within healthcare facility radiology networks to identify and prioritize non-contrast head CT (NCCT) scans based on algorithmically-identified findings of acute intracranial hemorrhage (aICH). The device, developed using computer vision and deep learning technologies, facilitates prioritization of CT scans containing findings of aICH. There are two main components of the software device: (1) the Accipiolx Agent and (2) the MaxQ-AI Engine. The Agent serves as an active conduit which receives head CT studies from a PACS and transfers them to the Engine. After successful processing of a case via the MaxQ-AI Engine, the Accipiolx Agent receives the Engine results and returns them to the PACS or workstation for use in worklist prioritization.

Accipiolx works in parallel to and in conjunction with the standard care of workflow. After a CT scan has been performed, a copy of the study is automatically retrieved and processed by Accipiolx. The device performs identification and classification of objects consistent with aICH, and provides a case-level indicator which facilitates prioritization of cases with potential acute hemorrhagic findings for urgent review.

Intended Use / Indications for Use

Accipiolx 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 in the acute care environment. Accipiolx analyzes cases using an artificial intelligence algorithm to identify

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

Accipiolx is not intended to direct attention to specific portions of an image or to anomalies other than acute intracranial hemorrhage. 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 cases.

Accipiolx and the predicate device (ContaCT) have the same intended use and substantially similar indications for use. Both devices are assistive software tools for diagnosis, designed to analyze brain CT images for findings suggestive of a pre-specified clinical condition -- specifically, cerebrovascular (CV) events. The subject device (Accipiolx) supports the rapid assessment of acute intracranial hemorrhage (aICH), while the predicate device assesses findings potentially indicative of large vessel occlusion (LVO). Since aICH and LVO are aspects of the same differential diagnosis and treatment considerations, the clinical purpose of the two devices is substantially equivalent; thus, both devices have the same intended use. In addition, the AiDoc Briefcase was recently cleared for use in assessment of ICH and thus is a relevant reference device to further demonstrate substantial equivalence of the subject device.

Summary of Technological Characteristics

The technological characteristics and mode of operation of the Accipiolx device are substantially equivalent to the predicate device.

Accipiolx and its predicate are DICOM-compliant software devices incorporated into the radiology infrastructure of a clinical center. Both employ algorithms developed through artificial intelligence methodologies to analyze brain CT images received from a CT scanner. Both software devices include an image management component and an image processing and analysis component (in Accipiolx, these are the Agent and the Engine, respectively).

Accipiolx was developed using a training set containing CT cases collected from multiple institutions and CT manufacturers. This training process included pilot development, optimization of object and feature identification, algorithmic training and selection/optimization of thresholds above which cases are considered positive.

In both the predicate and subject devices, the algorithm identifies applicable CT series' based on image parameters. In both devices, skull stripping and registration steps are performed, the relevant tissues are identified and segmented, and a feature identification process, which includes measures of hyperdensity compared to a pre-defined threshold, is performed. Findings above this threshold cause the software devices to generate a case-level identifier which is used for prioritization of cases based on a suspected cerebrovascular finding. With Accipiolx, the system output itself is the basis for prioritization within radiological workflow and viewing systems. In both cases, the procedure is performed in parallel to and in conjunction with the standard processing of image storage and availability for clinician assessment.

A summary table comparing the key features of the subject and predicate devices is provided below.

	Subject Device: MaxQ AI Accipiolx	Predicate Device: Viz.AI ContaCT
Notification-only, parallel workflow tool	Yes	Yes
Intended user	Hospital networks and trained clinicians	Hospital networks and trained clinicians
Setting	Acute care	Acute care
Identify patients with a pre-specified clinical condition	Yes	Yes
Clinical condition	Cerebrovascular Event: Intracranial hemorrhage	Cerebrovascular Event: Large vessel occlusion
Alert to finding	Yes; flagged for review	Yes; flagged for review
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist
Modality	Non-Contrast CT	CT Angiogram
Artificial Intelligence algorithm	Yes	Yes
Limited to analysis of imaging data	Yes	Yes
Non-Diagnostic Preview	No	Yes
Aids prompt identification of cases with indicated findings	Yes	Yes
Output	Suspected hemorrhage / No suspected hemorrhage	Suspected large vessel occlusion
Where results are received	PACS / Workstation	PACS / Mobile application

Performance Testing

MaxQ-AI conducted a retrospective study to test the sensitivity and specificity of Accipiolx in processing non-contrast head CT cases with a high or low probability of intracranial hemorrhage (ICH). Device sensitivity and specificity was compared to ground truth established by concurrence of at least two expert neuroradiologist readers.

Analysis of 360 cases collected from over 30 US sites demonstrated system sensitivity and specificity of 92% (95% CI: 87.29-95.68%) and 86% (95% CI: 80.18-90.81%), respectively. These results exceeded the predefined performance goals for sensitivity and specificity.

During performance testing, average per-case processing time was 4.1 minutes (95% CI: 3.8-4.3 minutes), which is comparable to the processing time reported by the reference BriefCase device.

Based on the software testing and clinical performance, Accipiolx has a safety and effectiveness profile that is similar to the predicate device for the proposed indications for use.

Conclusion

The Accipiolx device is as safe and effective as the ContaCT device. Accipiolx has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences do not alter the intended prioritization and triage use of the device and do not affect its safety and effectiveness when used as labeled, and also do not raise any new or different questions of safety or effectiveness. Performance data demonstrate that the software functions as intended. Thus, the Accipiolx is substantially equivalent.