MaxQ Al Ltd.                                                                 August 7, 2020
℅ Joshua Schulman, Ph.D.
Vice President, Clinical, Regulatory and Quality Affairs
96 Yigal Alon Street, 1st Floor
Tel Aviv, 6789140
ISRAEL

Re:  K201310
      Trade/Device Name:  Accipiolx
      Regulation Number:  21 CFR 892.2080
      Regulation Name:  Radiological computer aided triage and notification software
      Regulatory Class:  Class II
      Product Code:  QAS
      Dated:  May 15, 2020
      Received:  May 15, 2020

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/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: 06/30/2020
*See PRA Statement below*

510(k) Number *(if known)*

K201310

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)*

X 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

## MaxQ AI's Accipiolx

**Submitter**

MaxQ AI Ltd.
96 Yigal Alon Street,
Tel Aviv, Israel 6789140
Tel: +1-617-765-0333
Contact Person: Josh Schulman, Ph.D.

Date Prepared: May 15, 2020

**Name of Device:** Accipiolx

**Common or Usual Name/ Classification Name:**

Radiological Computer-Assisted Triage and Notification Software

**Regulatory Class:** Class II

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

**Predicate Device:** Accipiolx, K182177, Manufactured by MaxQ AI

**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, which utilizes deep learning technologies, facilitates prioritization of CT scans containing findings of aICH. Accipiolx receives CT scans identified by the Accipio Agent or other compatible Medical Image Communications Device (MICD), processes them using algorithmic methods involving execution of multiple computational steps to identify suspected presence of aICH, and generates a results file to be transferred by the Accipio Agent or a similar MICD device for output to a PACS system or workstation for 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.

## Summary of Technological Characteristics

The technological characteristics and principles of operation of the subject Accipiolx device are substantially equivalent to the predicate device, Accipiolx (K182177). The subject 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 head CT images received from a CT scanner.

The subject Accipiolx, like its predicate device, 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.

The subject device and the predicate device also have highly similar principles of operation: the software analyzes CT images and prioritizes cases for physician review when there is suspected aICH. In both the predicate and subject devices, the algorithm identifies applicable CT cases 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 device to generate a case-level identifier which is used for prioritization of cases based on a suspected cerebrovascular finding. The system output is used 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 and their availability for clinician assessment.

The algorithmic functionality of Accipiolx is substantially equivalent in all aspects to that of the predicate device and differs only with respect to the segmentation method used and inclusion of additional algorithmic features for enhanced detection of aICH. These improvement changes do not alter the safety and efficacy profile of the device.

The subject Accipiolx and the predicate device have the same intended use and indications for use. Both devices are assistive software tools, designed to analyze head CT images for findings suggestive of a pre-specified clinical condition -- specifically, aICH. Both the subject and predicate devices support the rapid assessment of aICH. For these reasons, the subject device is substantially equivalent to the predicate device.

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

| | Subject Device:<br>MaxQ AI Accipiolx | Predicate Device:<br>MaxQ AI Accipiolx<br>(K182177) |
|---|---|---|
| **Intended Use /<br>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.<br><br>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 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.<br><br>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. |
| **Population** | Adult patients (21 years of age and older) indicated for head CT | Adult patients (21 years of age and older) indicated for head CT |
| **Notification-only, parallel workflow tool** | Yes | Yes |
| **Intended users** | 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: Intracranial hemorrhage |
| **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 head CT | Non-Contrast head CT |
| **Artificial Intelligence algorithm** | Yes | Yes |
| **Software segmentation method** | CNN-based segmentation | Machine-vision based segmentation |
| **Case level assessment of clinical condition probability** | Yes – case-level assessment is derived both from detection of individual aICH findings and algorithmic assessment of the full case. | Yes – case-level assessment is derived from detection of individual aICH findings |

| Limited to analysis of imaging data | Yes | Yes |
|---|---|---|
| Non-Diagnostic DICOM Preview | No | No |
| Aids prompt identification and prioritization of cases with indicated findings | Yes | Yes |
| Medical systems/devices used in conjunction with the device | 1. Device is used with CT systems for DICOM input and with PACS systems, which may present/use the data. 2. Device is used with Medical Image Communications Devices (MICDs), such as the Accipio Agent, to receive native CT images for processing and to generate visual results | 1. Device is used with CT systems for DICOM input and with PACS systems, which may present/use the data. 2. Device is used with Medical Image Communications Devices (MICDs), such as the Accipio Agent, to receive native CT images for processing and to generate visual results |
| Output | Suspected hemorrhage / No suspected hemorrhage | Suspected hemorrhage / No suspected hemorrhage |
| Systems where results are displayed | PACS / Workstation | PACS / Workstation |
| Performance results | Sensitivity- 97% (95% CI: 92.8% - 98.8%) Specificity- 93% (95% CI: 88.6% - 96.6%) Processing time – 1.17 minutes (95% CI: 1.16 – 1.18 minutes) | Sensitivity - 92% (95% CI: 87.29 - 95.68%) Specificity - 86% (95% CI: 80.18 - 90.81%) Processing time – 4.1 minutes (95% CI: 3.8 - 4.3 minutes) |

**Performance Testing**

Performance testing was conducted using the same approach as that used for the predicate device. MaxQ AI conducted a retrospective study to test the clinical performance of Accipiolx in processing non-contrast head CT cases with a high or low probability of ICH. Performance of the device was analyzed based on validation testing results that were compared to the predefined performance goals.

- Analysis of 360 newly tested cases collected from multiple sites across 17 US states demonstrated device Sensitivity and Specificity of 97% (95% CI: 92.8% - 98.8%) and 93% (95% CI: 88.6% - 96.6%), respectively.

- Sensitivity for intra-axial and extra-axial hemorrhages was 100% (95% CI: 96.6% - 100%) and 92% (95% CI: 82.7% - 96.9%), respectively. Although the Sensitivity observed in the extra-axial subgroup was lower compared to the intra-axial subgroup, the result was still notably high, considering the fact that extra-axial hemorrhages are known to be more difficult for accurate assessment among radiologists.

- The average per-case processing time (confirmatory secondary endpoint) was 1.17 minutes (95% CI: 1.16 – 1.18 minutes), demonstrating that when using the subject Accipiolx for aICH prioritization, the intended users will have improved benefit in time saving compared to the predicate device.

- Analysis of additional accuracy parameters, tested as secondary endpoints, demonstrated NPV and PPV of 99.8% (95% CI: 99.7% - 100%) and 43.3% (95% CI: 25.9% - 53%), respectively. The very high NPV result reflects relatively very low probability of false positive results given by Accipiolx.

These results exceeded the predefined performance goals and demonstrated improved clinical performance, which is substantially equivalent to the predicate device.

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

**Conclusion**

The Accipiolx device is as safe and effective as its predicate device. Accipiolx has the same intended use and indications for use, very similar 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. Clinical testing demonstrates an improved performance profile and supports the intended software function. Thus, the subject Accipiolx is substantially equivalent to the predicate Accipiolx (K182177).