Zebra Medical Vision Ltd.
℅ Flair Bar
VP Operations
Shefayim Commercial Center, PO Box 25
Shefayim, 6099000
ISRAEL

June 13, 2019

Re: K190424
Trade/Device Name: HealthICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: May 14, 2019
Received: May 17, 2019

Dear Flair Bar:

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)*
K190424

Device Name
HealthICH

Indications for Use *(Describe)*
The Zebra Head CT triage device is a software workflow tool designed to aid the clinical assessment of adult non-contrast head CT cases with features suggestive of intracranial hemorrhage in the medical care environment. HealthICH 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. HealthICH is not intended to direct attention to specific portions of an image or to anomalies other than 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510 (k) Summary

510(K) Summary - HealthICH
Zebra Medical Vision Ltd.

510(k) Number – K190424

I. Applicant's Name: Zebra Medical Vision Ltd.
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Telephone: +972-9-8827795
Fax: +972-9-8827795

Date Prepared: May 14, 2019

II. Device

Trade Name: HealthICH

Classification Name:
Radiological Computer-Assisted Triage and Notification Software

Regulation Number:
892.2080

Classification:
Class II, Radiology

Product Code:
QAS

III. Predicate Device:

The HealthICH device is substantially equivalent to the following device:

Proprietary Name	Accipiolx
Premarket Notification	K182177
Classification Name	Radiological Computer-Assisted Triage and Notification Software
Regulation Number	21 CFR 892.2080
Product Code	QAS
Regulatory Class	II

IV. Device Description

Zebra's HealthICH solution is a software product that automatically identifies suspected finding suggestive of Intracranial Hemorrhage and notifies the PACS/workstation of the presence of this critical finding in the scan. This notification allows for worklist prioritization of the identified scan and assists clinicians in viewing the prioritized scan before others. The device aim is to aid in the prioritization and triage of radiological medical images only.

Zebra's HealthICH Triage Device uses an artificial intelligence algorithm to analyze CT scans. The HealthICH is indicated for the analysis of non-contrast head CT scans. The algorithm output does not include an image and therefore it does not mark, highlight or direct users' attention to a specific location on the original CT scan.

The Zebra's HealthICH device works in parallel to and in conjunction with the standard of care workflow. After a head CT scan has been performed, a copy of the study is automatically retrieved and processed by the HealthICH device. The device performs the analysis of the study and return a notification about a suspected finding suggestive of Intracranial Hemorrhage to the PACS/workstation which prioritizes it through its worklist interface. The clinician is then able to review the study earlier than in standard of care workflow.

The primary benefit of the product is the ability to reduce the time it takes to notify physician to the presence of a critical finding such as suspected Intracranial Hemorrhage in the head CT scan.

The software does not recommend treatment or provide a diagnosis. It is designed as tool to assist the medical staff and hospital networks in workflow triaging by highlighting and prioritizing studies containing suspected findings. The final diagnosis is provided by a radiologist or other qualified physician after examining the original scan as determined by the clinical standard of care. The software is intended for use by radiologists and other qualified medical staff who read head CT scans on a regular basis

The following modules compose the HealthICH software:
Data input and validation: Following retrieval of a study, the validation feature assessed the input data (i.e. age, modality, view) to ensure compatibility for processing by the algorithm.
HealthICH algorithm: Once a study has been validated, the algorithm analyzes the head CT for identification of suspected finding suggestive of intracranial hemorrhage.
IMA Integration feature:
HealthICH interacts with users through the PACS/workstation via the Zebra Imaging Analytics platform (IMA). It does not have a Graphical User Interface (GUI). The HealthICH sends the results of the study analysis to the Zebra Imaging Analytics Platform, which then distributes the HealthICH results to the PACS/workstation for prioritization
Error codes feature: In the case of a study failure during data validation or the analysis by the algorithm, an error is provided to the Zebra Imaging Analytics Platform

V. Intended Use/Indication for Use:

The Zebra Head CT triage device is a software workflow tool designed to aid the clinical assessment of adult non-contrast head CT cases with features suggestive of intracranial hemorrhage in the medical care environment. HealthICH 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. HealthICH is not intended to direct attention to specific portions of an image or to anomalies other than 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.

VI. Comparison of Technological Characteristics Compared to Predicate Device:

The technological characteristics, e.g., overall design, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the HealthICH device are substantially equivalent to the predicate device cited above.

A comparison of the technological characteristics with the predicate device is summarized below.

Technological Characteristics	Proposed Device: HealthICH	Predicate Device: Accipiolx (K182177)	Summary
Intended Use	The Zebra Head CT triage device is a software workflow tool designed to aid the clinical assessment of adult non-contrast head CT cases with features suggestive of intracranial hemorrhage in the medical care environment. HealthICH 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. HealthICH is not intended to direct attention to specific portions of an image or to anomalies other than 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.	AccipioIx 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. AccipioIx 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. AccipioIx 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	Same

		preclude clinical assessment of CT cases.	
Notification-only, parallel workflow tool	Yes	Yes	Same
User	Prespecified clinical users (clinicians)	Prespecified clinical users (clinicians)	Same
Radiological images format	DICOM	DICOM	Same
Identify patients with prespecified clinical condition	Yes	Yes	Same
Clinical condition	Intracranial hemorrhage	Intracranial hemorrhage	Same
Alert to finding	Yes; flagged for review	Yes; flagged for review	Same
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist	Same
Modality	CT	CT	Same
Body part	Head	Head	Same
Artificial Intelligence algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Aids prompt identification of cases with indicated findings	Yes	Yes	Same
Where results are received	PACS / Workstation	PACS / Workstation	Same

VII. Performance Data:

The HealthICH has been evaluated and verified in accordance with software specifications and applicable performance standards through Software Development and Validation & Verification Process to ensure performance according to specifications, User Requirements and Federal Regulations and Guidance documents, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

The performance of the HealthICH device has been validated in retrospective stand-alone performance study that was carried out in a simulated synthetics work-flow consisting of truthed validation data. The data included a retrospective cohort of 427 anonymized head CT cases from USA and Israel, including intracranial hemorrhage positive (n=199) and negative cases (n=228), as well as confounding imaging factors. The data included cases of both genders (Male N=242, Female N=185) and subjects aging from 18-102 years old.

The validation set was truthed (ground truth) by two US Board Certified neuro-radiologists (truthers). In the event that the two ground truthers did not agree, a third, more senior US Board Certified neuro-radiologist reviewed the axial CT series and determined ground truth (presence or absence of ICH). The stand-alone detection accuracy was measured on this cohort respective to ground truth. The triage effectiveness was evaluated by the standalone per-case processing time of the device.

The standalone performance testing demonstrated the substantial equivalence of the HealthICH software effectiveness as compared to the predicate device (Accipiolx, K182177). Specifically, the HealthICH triage time (per-case "processing time") was reported as an average 48.67 seconds (95% CI: 47.06, 50.28). This is similar to that reported by the predicate (4.1 minutes (95% CI: 3.8-4.3 minutes).

Additionally, the HealthICH triage accuracy was similar to that reported by the predicate (HealthICH sensitivity and specificity of 94.47% (95% CI: 90.32-97.21%) and 92.54% (95% CI: 88.33-95.60%), respectively, and predicate sensitivity and specificity of 92% (95% CI: 87.29-95.68%) and 86% (95% CI: 80.18-90.81%), respectively). Furthermore, the subject device had a reported overall agreement of 93% (95% CI: 90.66, 95.60) compared to the ground truth, as calculated for the cohort of 199 ICH-positive and 228 ICH-negative cases (N=427). Users should note that in clinical practice, the ratio between positive and negative cases varies due to the natural prevalence, and therefore overall agreement may differ. No adverse events were reported.

The performance testing of the HealthICH device establishes that the subject device is both safe and effective. This established that the HealthICH device meets its intended use statement and is substantially equivalent to the predicate device.

VIII. Conclusion:

The subject HealthICH device and the Accipiolx predicate device are both software-only devices intended to aid in triage of radiological images, independent of standard of care workflow. The labeling of both devices are limited to the categorization of exams and are not to be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

Both devices operate in parallel to the standard of care workflow in the sense that they do not change the original image, do not provide any marking, and do not remove cases from the standard of care. The minor differences between the subject device and the predicate raise no new issues of safety or effectiveness. In addition, performance testing demonstrates that the HealthICH performs

as intended. The HealthICH device is therefore substantially equivalent to the Accipiolx predicate device.