Zebra Medical Vision Ltd.
℅ Ms. Flair Bar
VP Operations and QA/RA
Shefayim Commercial Center
PO Box 25
Shefayim, 6099000
ISRAEL

May 12, 2020

Re: K192901
Trade/Device Name: HealthVCF
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer-assisted prioritization software
Regulatory Class: Class II
Product Code: QFM
Dated: April 2, 2020
Received: April 8, 2020

Dear Ms. 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)*
K192901

Device Name
HealthVCF

Indications for Use *(Describe)*
HealthVCF is a passive notification for prioritization-only, parallel-workflow software tool used by clinicians to prioritize specific patients within the standard-of-care bone health setting for suspected vertebral compression fractures. HealthVCF uses an artificial intelligence algorithm to analyze chest and abdominal CT scans and flags those that are suggestive of the presence of at least one vertebral compression at the exam level. These flags are viewed by the clinician in Bone Health and Fracture Liaison Service programs in the medical setting via a worklist application on their Picture Archiving and Communication System (PACS). HealthVCF does not send a proactive alert directly to the user.
HealthVCF does not provide diagnostic information beyond triage and prioritization, it does not remove cases from the radiology worklist, and should not be used in place of full patient evaluation, or relied upon to make or confirm diagnosis.

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 - HealthVCF
Zebra Medical Vision Ltd.

510(k) Number –K192901

I. Applicant's Name:

Zebra Medical Vision Ltd.
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PO Box 25
Shefayim, 6099000
ISRAEL
Telephone: +972-9-8827795
Fax: +972-9-8827795

Date Prepared: May 07, 2020

II. Device

Trade Name: HealthVCF

Classification Name:
QFM - Radiological Computer-Assisted Prioritization Software

Regulation Number:
892.2080

Classification:
Class II, Radiology

III. Predicate Device:

The HealthVCF device is substantially equivalent to the following device:

Proprietary Name	CmTriage
Premarket Notification	K183285
Classification Name	Radiological Computer-Assisted Prioritization Software
Regulation Number	21 CFR 892.2080
Product Code	QFM
Regulatory Class	II

IV. Device Description

Zebra's HealthVCF solution is a software product that automatically identifies suspected findings suggestive of vertebral compression fractures on chest and abdominal CT scans and provides a passive notification to the workstation of the presence of this finding in the scan. This notification is received by the standalone desktop Zebra Worklist application which flags the identified scan and assists clinicians engaged in bone-health management in viewing the scan ahead of others. The device aim is to aid in prioritization and triage of radiological medical images only and does not provide diagnostic information beyond triage.

The software uses an artificial intelligence algorithm to automatically analyze chest and abdominal CT scans. If a suspected vertebral compression fracture is found in a scan, the alert is automatically sent to the Zebra Worklist application on the workstation used by the bone-health clinician in parallel with the ongoing standard of care within the bone health setting. The standard of care radiology workflow (i.e. reviewing and reporting the findings that initiated the request for CT) continues unaffected by the parallel workflow of the bone health program. For clarity, the HealthVCF device does not flag/prioritize cases within this radiology workflow. The standalone desktop application, Zebra Worklist, includes three sagittal preview images meant for informational purposes only and is not intended for diagnostic use. The Zebra Worklist presents all cases processed by the algorithm, and flags those with a suspected finding.

Zebra's HealthVCF device works in parallel to and in conjunction with the standard care of workflow within bone health programs, and completely independent of the standard of care workflow within the radiology department. After a chest or abdominal CT scan has been performed, a copy of the study is automatically retrieved and processed by the HealthVCF device. The device performs the analysis of the study and returns a notification about a suspected vertebral compression fractures to the Zebra Worklist to notify the clinicians in Bone Health and Fracture Prevention Programs reviewing the chest and abdominal CTs for at-risk patients. The clinician is then able to review the study earlier and recall the patient for further evaluation.

The primary benefit of the product is the ability to reduce the time it takes to alert physicians to the presence of a finding such as a vertebral compression fracture. The software does not recommend treatment or provide a diagnosis. It is meant as a tool to assist in improved workload prioritization of cases in bone health and fracture prevention programs. The final diagnosis is provided by a clinician after reviewing the scan itself.

The following modules compose the HealthVCF 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.
HealthVCF algorithm: Once a study has been validated, the algorithm analyzes the chest and abdominal CT scans for detection of suspected finding suggestive of vertebral compression fracture.

IMA Integration feature: The study analysis and the results of a successful study analysis is provided to IMA, to then be sent to Zebra Worklist application for triaging.
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 system.

V. Intended Use/Indication for Use:

HealthVCF is a passive notification for prioritization-only, parallel-workflow software tool used by clinicians to prioritize specific patients within the standard-of-care bone health setting for suspected vertebral compression fractures. HealthVCF uses an artificial intelligence algorithm to analyze chest and abdominal CT scans and flags those that are suggestive of the presence of at least one vertebral compression at the exam level. These flags are viewed by the clinician in Bone Health and Fracture Liaison Service programs in the medical setting via a worklist application on their Picture Archiving and Communication System (PACS). HealthVCF does not send a proactive alert directly to the user.
HealthVCF does not provide diagnostic information beyond triage and prioritization, it does not remove cases from the radiology worklist, and should not be used in place of full patient evaluation, or relied upon to make or confirm diagnosis.

VI. 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 HealthVCF device are substantially equivalent to the predicate device cited above.
A comparison of the technological characteristics with the predicate is summarized below.

Technological Characteristics	Proposed Device HealthVCF	Predicate Device cmTriage (K183285)	Summary
Indication for Use/Intended Use	HealthVCF is a passive notification for prioritization-only, parallel-workflow software tool used by clinicians to prioritize specific patients within the standard-of-care bone health setting for suspected vertebral compression fractures. HealthVCF uses an artificial intelligence algorithm to analyze chest and abdominal CT scans and flags those that are	cmTriage is a passive notification for prioritization-only, parallel-workflow software tool used by radiologists to prioritize specific patients within the standard-of-care image worklist for 2D FFDM screening mammograms. cmTriage uses an artificial intelligence algorithm to analyze 2D FFDM screening mammograms and flags those that are suggestive of the presence of at least one suspicious finding at the	Similar expect for anatomy, imaging modality, and lesion type

	suggestive of the presence of at least one vertebral compression at the exam level. These flags are viewed by the clinician in Bone Health and Fracture Liaison Service programs in the medical setting via a worklist application on their Picture Archiving and Communication System (PACS). HealthVCF does not send a proactive alert directly to the user. HealthVCF does not provide diagnostic information beyond triage and prioritization, it does not remove cases from the radiology worklist, and should not be used in place of full patient evaluation, or relied upon to make or confirm diagnosis.	exam level. These flags are viewed by the radiologist via their Picture Archiving and Communication System (PACS) worklist. The decision to use cmTriage codes and how to use cmTriage codes is ultimately up to the radiologist. cmTriage does not send a proactive alert directly to the radiologist. Radiologists are responsible for reviewing each exam on a diagnostic viewer according to the current standard of care. cmTriage is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the radiologist's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis. cmTriage is for prescription use only.	
Notification-only, parallel workflow tool	Yes	Yes	Same
User	Bone Health Clinician	Radiologist	Different, but both users include a "*designated list of clinicians"* per 21 CFR 892.2080
Identify patients with prespecified clinical condition	Yes	Yes	Same
Clinical condition	Vertebral compression fracture	Breast Cancer	Different but both findings suggestive of a pre-specified clinical condition
Alert to finding	Yes; notification flagged for review	Yes; notification 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	FFDM screening mammograms	Different, but both run on *"radiological*

			medical images" per 21 CFR 892.2080
Body part	Chest and abdomen	Breast	Different anatomical sites but both *"operates on radiological images of the human body"* per 21 CFR 892.2080.
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:

Safety and performance of HealthVCF 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 HealthVCF device has been validated in a performance study for triage of chest and abdominal CT cases. The data included a retrospective cohort of 611 anonymized Chest and abdominal CT cases from the USA and Israel, including 306 cases positive for vertebral compression fractures (severe and moderate fractures) and 305 cases negative for vertebral compression fractures (mild or no fracture), as well as confounding imaging factors. The validation data set was truthed (ground truth) by three US Board-Certified Radiologists (truthers). The stand-alone detection accuracy was measured on this cohort respective to the ground truth.

The HealthVCF device detection accuracy met the accuracy performance goals for AUC, sensitivity, and specificity. Overall, the HealthVCF was able to demonstrate an area under the curve (AUC) of 0.9504 (95% CI: [0.9348, 0.9660), which is both comparable to the predicate device, and meets the required technical method under the QFM product code. The device establishes effective triage based on an AUC >95%. The HealthVCF performance met the performance goal and demonstrated high performance substantially equivalent to the predicate

device. The reported results for this operating point was a sensitivity of 90.20% (95% CI: [86.35%;93.05%]) and specificity was 86.89% (95% CI: [82.63%;90.22%]).
In addition, we assessed the performance time of the HealthVCF that reflects the time it takes for the device to analyze the study. The average performance time of the HealthVCF was 61.36 seconds, a timing performance that is substantially equivalent to the predicate.

VIII. Conclusion

The subject HealthVCF device and the cmTriage predicate device are both software-only devices intended to aid in triage of radiological images, independent and in-parallel 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 HealthVCF performs as intended. The HealthVCF device is therefore substantially equivalent to the cmTriage predicate.