Zebra Medical Vision Ltd.   July 16, 2020
℅ Flair Bar
VP Operations
Shefayim Commercial Center,
P.O. Box 25
Shefayim, 6099000
ISRAEL

Re: K200905
   Trade/Device Name: HealthMammo
   Regulation Number: 21 CFR 892.2080
   Regulation Name: Radiological computer aided triage and notification software
   Regulatory Class: Class II
   Product Code: QFM
   Dated: June 17, 2020
   Received: June 22, 2020

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)*
K200905

Device Name
HealthMammo

Indications for Use *(Describe)*
The Zebra HealthMammo is a passive notification for prioritization-only, parallel-workflow software tool used by MQSA-qualified interpreting physicians to prioritize patients with suspicious findings in the medical care environment. HealthMammo utilizes 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 exam-level. HealthMammo produces an exam-level output to a PACS/Workstation for flagging the suspicious case and allows worklist prioritization.

MQSA-qualified interpreting physicians are responsible for reviewing each exam on a display approved for use in mammography according to the current standard of care. HealthMammo device is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the interpreting physician's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis.

The HealthMammo device is intended for use with complete 2D FFDM mammography exams acquired using validated FFDM systems only.

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.

5. 510 (k) Summary

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

510(k) Number – K200905

I. **Applicant's Name:**   Zebra Medical Vision Ltd.
Shefayim Commercial Center
PO Box 25
Shefayim, 6099000
ISRAEL
Telephone: +972-9-8827795
Fax: +972-9-8827795

Date Prepared: July 13, 2020

II. **Device**

Trade Name: HealthMammo

Classification Name:
QFM - Radiological Computer-Assisted Prioritization Software

Regulation Number:
892.2080

Classification:
Class II, Radiology

III. **Predicate Device:**

The HealthMammo 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 HealthMammo solution is a software product that automatically analyzes 2D FFDM screening mammograms and notifies PACS/workstation of the presence of suspicious findings in

the scan. This passive-notification allows for worklist prioritization of the specific scan and assists clinicians in viewing prioritized scans before others. The device aim is to aid in prioritization and triage of radiological medical images only. It is a software tool for MQSA interpreting physicians reading mammograms and does not replace complete evaluation according to the standard of care.

The Zebra's HealthMammo device works in parallel to and in conjunction with the standard care of workflow. After a mammogram has been performed, a copy of the study is automatically retrieved and processed by the HealthMammo device. The device performs the analysis of the study and returns a notification about suspected finding to the PACS/workstation which flags it through the worklist interface or alternatively, the Zebra Worklist will notify the user through a desktop application. 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 alert physicians to the presence of a suspicious finding. The software does not recommend treatment or provide a diagnosis. It is meant as a tool to assist in improved workload prioritization of suspicious cases. The final diagnosis is provided by a clinician after reviewing the scan itself..

The following modules compose the HealthMammo 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.
HealthMammo algorithm: Once a study has been validated, the algorithm analyzes the 2D FFDM screening mammogram for detection of suspected findings.
IMA Integration feature: The study analysis and the results of a successful study analysis is provided to IMA, to then be sent 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 system.

V.   Intended Use/Indication for Use:

The Zebra HealthMammo is a passive notification for prioritization-only, parallel-workflow software tool used by MQSA-qualified interpreting physicians to prioritize patients with suspicious findings in the medical care environment. HealthMammo utilizes 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 exam-level. HealthMammo produces an exam-level output to a PACS/Workstation for flagging the suspicious case and allows worklist prioritization.

MQSA-qualified interpreting physicians are responsible for reviewing each exam on a display approved for use in mammography according to the current standard of care. HealthMammo device is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the interpreting physician's

worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis.

The HealthMammo device is intended for use with complete 2D FFDM mammography exams acquired using validated FFDM systems only.

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 HealthMammo 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 HealthMammo	Predicate Device cmTriage (K183285)	Summary
Indication for Use/Intended Use	The Zebra HealthMammo is a passive notification for prioritization-only, parallel-workflow software tool used by MQSA-qualified interpreting physicians to prioritize patients with suspicious findings in the medical care environment. HealthMammo utilizes 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 exam-level. HealthMammo produces an exam-level output to a PACS/Workstation for flagging the suspicious case and allows worklist prioritization. MQSA-qualified interpreting physicians are responsible for reviewing each exam on a display approved for use in mammography according to the current standard of care. HealthMammo device is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the interpreting physician's worklist, and should not be used in lieu of full patient evaluation, or relied upon to	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 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	Same

	make or confirm diagnosis. The HealthMammo device is intended for use with complete 2D FFDM mammography exams acquired using validated FFDM systems only.	diagnosis. cmTriage is for prescription use only.	
Notification-only, parallel workflow tool	Yes	Yes	Same
User	Interpreting physician	Radiologist	Same
Identify patients with prespecified clinical condition	Yes	Yes	Same
Alert to finding	Yes; passive notification flagged for review	Yes; passive 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	FFDM screening mammograms	FFDM screening mammograms	Same
FFDM manufacturer	Hologic	Vendor agnostic	Different, the subject device processes 2D FFDM scans acquired by Hologic systems, while the predicate device may receive scans acquired from alternative vendors.
Body part	Breast	Breast	Same
Artificial Intelligence algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Inclusion Criteria	- 2D FFDM screening mammograms - Biopsy proven cancer studies (soft tissues and micro-calcifications) - BIRADS 1 and 2 normal cases with 2 year follow-up Studies with 4 standard views (LCC, LMLO, RCC, RMLO)	- 2D FFDM screening mammograms - Biopsy proven cancer studies (soft tissues and micro-calcifications) - BIRADS 1 and 2 normal cases with 2 year follow-up Studies with 4 standard views (LCC, LMLO, RCC, RMLO)	Same
Exclusion Criteria	- Studies that do not include all 4 views	- Studies that do not include all 4 views	Same

	- Digital Breast tomosynthesis studies - 3D studies Studies that do not comply with the inclusion criteria	- Digital Breast tomosynthesis studies - 3D studies Studies that do not comply with the inclusion criteria	
Aids prompt identification of cases with indicated findings	Yes	Yes	Same
Multiple operating points	Yes; 3 optional operating points	No; single operating point	Different, HealthMammo provides an additional 2 operating points. Performance complies with DEN 170073 Special control 1(iii).
Preview Images	Presentation of notification and preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains the default option for all cases.	Presentation of notification and preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains the default option for all cases.	Same
Where results are received	PACS / Workstation	PACS / Workstation	Same

VII. Performance Data:

Safety and performance of HealthMammo 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 HealthMammo device has been validated in a performance study for triage of 2D FFDM screening mammogram cases. The data included a retrospective cohort of 835 anonymized 2D FFDM screening mammograms from the USA, UK, and Israel, including 435 cases positive with biopsy confirmed cancers and 400 cases negative for breast cancer (BIRADS1 and BIRADS2 with a two-year follow up of a negative diagnosis), as well as confounding variables.

The test set was constructed to ensure that confounding factors present in the population were addressed in the data and consistent with the population of women undergoing breast cancer screening. Confounding factors that were considered include: 1) Lesion Type; 2) Breast Density

3) Age; and 4) Histology Type. The stand-alone detection and triage accuracy was measured on this cohort versus the ground truth.

The HealthMammo device detection accuracy was validated for three different operating points and met the prespecified performance goals for accuracy in terms of the AUC as well as sensitivity, and specificity for all defined operating points. Overall, the HealthMammo was able to demonstrate an area under the ROC curve (AUC) of 0.9661 (95% CI: [0.9552, 0.9769]), which is comparable with the predicate device, and exceeds the required technical method under the QFM product code for effective triage with an AUC >95%.

Sensitivity and Specificity goals were set based on the performance in the Breast Cancer Surveillance Consortium (BCSC) study and compared to the performance of the predicate device, CmTriage (K183285). The "standard mode," "high specificity," and "high sensitivity" operating points correspond to the reported human performance in the BCSC study, and are also established by the predicate device.

Sensitivity and specificity of the HealthMammo was reported for the three operating points, all of which met their performance goals. The first operating point, "standard mode," reported a sensitivity of 89.89% (95% CI: [86.69%;92.38%]) and a specificity of 90.75% (95% CI: [87.51%;93.21%]). The second operating point, "high sensitivity" reported a sensitivity of 94.02% (95% CI: [91.39%;95.89%]) and a specificity of 83.50% (95% CI: [79.55%;86.82%]). The "high specificity" operating point, reported a sensitivity of 84.14% (95% CI: [80.41%;87.27%]) and a specificity of 94.00% (95% CI: [91.23%;95.94%]). These three operating points demonstrated good performance compared with the standard of care reported in the BCSC study, and were found substantially equivalent to the predicate device (K183285).

Furthermore, we assessed the processing time of the HealthMammo which reflects the time it takes for the device to analyze the study and send a notification to the worklist. The average processing time of the HealthMammo was 2.9 minutes, a timing that is substantially equivalent to the predicate.

VIII. Conclusion

The subject HealthMammo device and the CmTriage predicate device (K183285) are both software-only devices intended to aid in triage of radiological images, within the 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, 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 HealthMammo performs as

intended. The HealthMammo device is therefore substantially equivalent to the CmTriage predicate.