Zebra Medical Vision Ltd.
% Matan Neeman
Director, Quality and Regulatory
Shefayim Commercial Center
PO Box 25
Shefayim, 6099000
ISRAEL

June 13, 2018

Re: K172983
Trade/Device Name: HealthCCS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 19, 2018
Received: May 22, 2018

Dear Matan Neeman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K172983

Device Name
HealthCCS

Indications for Use *(Describe)*
The HealthCCS Device is intended for use as a non-invasive post-processing software that can be used to evaluate calcified plaques in the coronary arteries, which may be a risk factor for coronary artery disease. The software can be used to generate reports of the total risk category of coronary calcium. This information can then be used by a physician for further analysis and treatment. The HealthCCS Device analyses pre-existing heart or chest ECG-Gated/Triggered CT scans. The Device is indicated for use only on patients whose age at the time, when the CT scan was taken, was above 20 years old. This device generates a 4-category Agatston-equivalent risk score, and the patient management, especially for the patient with the score from 0-10, will depend on the physician's own judgment. It may require further testing to evaluate the appropriate clinical management.

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 - HealthCCS
Zebra Medical Vision Ltd.

510(k) Number K172983

Applicant's Name: Zebra Medical Vision Ltd.
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Date Prepared: 06 June 2018

Trade Name: HealthCCS

Classification Name:
JAK - Computed tomography x-ray system

Classification:
Class II, Radiology

Predicate Device:
The HealthCCS device is substantially equivalent to the following device:

Proprietary Name	CSCS-001A Calcium Scoring Package
Premarket Notification	K072737 (5 Oct. 2007)
Classification Name	Computed tomography x-ray system
Regulation Number	21 CFR 892.1750
Product Code	JAK
Regulatory Class	II

Reference Device:

Proprietary Name	Kodak Carestream PACS
Premarket Notification	K053347
Classification Name	Picture archiving and communications system
Regulation Number	892.2050
Product Code	LLZ
Regulatory Class	II

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Indication for Use:

The HealthCCS Device is intended for use as a non-invasive post-processing software that can be used to evaluate calcified plaques in the coronary arteries, which may be a risk factor for coronary artery disease. The software can be used to generate reports of the total risk category of coronary calcium. This information can then be used by a physician for further analysis and treatment. The HealthCCS Device analyses pre-existing heart or chest ECG-Gated/Triggered CT scans. The Device is indicated for use only on patients whose age at the time, when the CT scan was taken, was above 20 years old. This device generates a 4-category Agatston-equivalent risk score, and the patient management, especially for the patient with the score from 0-10, will depend on the physician's own judgment. It may require further testing to evaluate the appropriate clinical management.

Device Description:

The HealthCCS Device is an automatic non-invasive post processing tool that uses cardiac CT images to identify and quantify calcification in the coronary arteries, known to be a risk factor for coronary disease.

HealthCCS Device quantifies calcification on non-contrast cardiac computed tomography (CT) scans. HealthCCS Device calculates the amount of identified calcification and

reports the risk category of coronary calcium. This information can then be used by a physician for further analysis and treatment.

The following quantification and data-reporting functionalities are provided by the HealthCCS Device:

Quantification:

- Calcification is automatically identified based on voxel density above a predefined threshold (130HU)
- A CNN-based probability threshold is then applied to the identified calcification to determine the likelihood that the calcium is associated within the coronary arterial distribution.
- Coronary Artery Calcium score is calculated for each study series using the Agatston method
- If a single study contains more than one series for which Coronary Artery Calcium score is calculated, the results from these series are averaged to give a Agatston equivalent score for the study

Data reporting:

- Generate patients' reports with their respective calcium score category

Performance Data:

Safety and performance of HealthCCS device has been evaluated and verified in accordance with software specifications and applicable performance standards. Software Development and Validation & Verification Processes have been implemented to ensure performance according to specifications, User Requirements and Federal Regulations and Guidance document: "General Principles of Software Validation".

The performance of the HealthCCS device has been validated in a retrospective performance study (n=249 studies), where the agreement between the 4-level risk categorization of the Health CCS device has been compared to the ground truth (GT) categorization by 3 radiologists using the Kodak Carestream PACS device (K053347). Adequate overall agreement of 0.89 (95% CI: [0.85, 0.92]) as well as adequate agreement per category were reported. The reproducibility was assessed on 150 studies that were

read three times. All Agatston equivalent scores per study ID were found identical over all three readings.

With respect to the specified requirements of accuracy, precision, and reproducibility, the obtained results have been found to be acceptable. The performance validation study demonstrated that HealthCCS device, provides accurate calcium scoring as compared to a reference device that shares the same intended use and technological characteristics as the predicate device that is currently marketed.

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 HealthCCS device are substantially equivalent to the predicate device cited above.
A comparison of the technological characteristics with the predicate and reference devices is summarized below.

Technological Characteristics	**Proposed Device: HealthCCS software tool**	**Predicate Device: CSCS-001A, Calcium Scoring Package (K072737)**	**Reference Device Kodak Carestream PACS (K053347)**	**Summary**
General				
Modality	CT	CT	CT	Same
Image format	DICOM	DICOM	DICOM	Same
Supported Computed Tomography (CT) scan – body part	Heart/Chest	Heart/Chest	Heart/Chest	Same
Supported Computed Tomography (CT) scan – dose	Typically Normal Dose	Typically Normal Dose	Typically Normal Dose	Same
Supported Computed Tomography (CT) scan – Use of IV contrast	No	No	No	Same

Supported Computed Tomography (CT) scan – ECG Gating/Triggering	ECG-Gated	ECG-Gated	ECG-Gated	Same
Quantification				
Calcification location marking	Automatic	Semi-automatic, Manual	Semi-automatic, Manual	Substantially equivalent
Selection of a calcified plaques based on voxel identification above a known threshold	Yes	Yes	Yes	Same
Default threshold of Calcium	130 HU (Hounsfield Units)	130 HU (Hounsfield Units)	130 HU (Hounsfield Units)	Same
Spatial threshold	1.5 mm^2	1 mm^2	1 mm^2	Substantially equivalent
Coronary Calcification calculation method	Agatston equivalent score based on the Agatston method	– Agatston score – Mass score – Volume score	– Agatston score – Mass score – Volume score	Substantially equivalent
Computed calcium scoring	Total calcium score	Total calcium score, and per-artery calcium score	Total calcium score, and per-artery calcium score	Substantially equivalent
Data reporting				
Generate patient report	Yes	Yes	Yes	Same
Printable hard copy reports	No	Yes	Yes	Substantially equivalent
Maintain a patient database for future reference	No	Yes	Yes	Substantially equivalent
Report of the calcium score category	Yes	Yes	Yes	Substantially equivalent

Substantial Equivalence:

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, HealthCCS

device raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy and performance.

The results of the performance comparison study demonstrated that the HealthCCS device performs as intended, in the specified use conditions, similarly to the reference device. The HealthCCS device is therefore substantially equivalent to the predicate device as the reference device and the predicate device share the same intended use and equivalent technological characteristics.