Zebra Medical Vision Ltd.   December 4, 2020
℅ Flair Bar
VP Operations
Shefayim Commercial Center
PO Box 25
Shefayim, 6099000
ISRAEL

Re: K202487
     Trade/Device Name: HealthJOINT
     Regulation Number: 21 CFR 892.2050
     Regulation Name: Picture archiving and communications system
     Regulatory Class: Class II
     Product Code: LLZ
     Dated: November 3, 2020
     Received: November 6, 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

510(k) Number *(if known)*
K202487

Device Name
HealthJOINT

Indications for Use *(Describe)*
The Zebra HealthJOINT device is a software tool for 3D reconstruction of bones from a set of 2D radiographs. The device is intended for assisting clinicians in the preoperative planning of knee orthopedic surgical procedures. Zebra's HealthJOINT analyzes cases using an artificial intelligence algorithm for the 3D model reconstruction. In addition to the model, the software provides a list of anatomical landmarks with their position on the 3D model.
The result is made available via a 3rd parties' software interface for further display and analysis of the 3D bone model.
Clinical judgement and experience are required to properly use the models produced by this software.

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 - HealthJOINT
Zebra Medical Vision Ltd.

510(k) Number – K202487

Applicant's Name: Zebra Medical Vision Ltd.
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Date Prepared: November 03, 2020

Trade Name: HealthJOINT

Classification Name:
LLZ – Picture Archiving and Communication System

Classification:
Class II, Radiology

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

Proprietary Name	Efficient Care 3D Planning
Premarket Notification	K183544
Classification Name	Picture Archiving and Communication System
Regulation Number	21 CFR 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.

Intended Use/Indication for Use:

The Zebra HealthJOINT device is a software tool for 3D reconstruction of bones from a set of 2D radiographs. The device is intended for assisting clinicians in the preoperative planning of knee orthopedic

surgical procedures. Zebra's HealthJOINT analyzes cases using an artificial intelligence algorithm for the 3D model reconstruction. In addition to the model, the software provides a list of anatomical landmarks with their position on the 3D model.

The result is made available via a 3rd parties' software interface for further display and analysis of the 3D bone model.

Clinical judgement and experience are required to properly use the models produced by this software.

Device Description:

Zebra's HealthJOINT device is a software product that uses an artificial intelligence algorithm to analyze X-ray scans. The HealthJOINT is indicated for the analysis of X-rays scans. The device receives a set of 2D radiographs and automatically provides a 3D model of the bones together with a list of anatomical landmarks with their position on the 3D model. The 3D model may be used by physicians for pre-operative planning of knee orthopedic surgeries. The HealthJoint supports 3D reconstructions of healthy bones, and osteoarthritis patients graded 1 to 4 based on the Kellgren-Lawrence grading system.

The HealthJOINT device functions as a component that can be used by 3rd parties via an API to generate the 3D models and provides a list of anatomical landmarks with their position on the 3D model. The software communicates with the API only, and is not user-facing. The software does not recommend clinical decisions or treatment.

The software is intended for use by clinicians in conjunction with additional patient information and professional judgment.

The following modules compose the HealthJoint software:

Data input and validation: performs validation of the input, X-ray DICOM images, assesses the input data (i.e. age, modality, view) to ensure compatibility for processing by the algorithm.

HealthJoint algorithm: Once the study has been validated the algorithm analyzes the AP (anterior-posterior) along with the LAT (lateral) knee X-ray study in order to provide 3D bone models and locations of anatomic landmarks.

IMA Integration feature: provides the capability to post studies for processing, get the study analysis status and the results of successful study analysis via a Web API.

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 calling 3rd party via the Web API.

Performance Data:

Safety and performance of HealthJOINT 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 HealthJOINT device performance was evaluated in a stand-alone retrospective study for accuracy of the 3D model of the Femur, Tibia, and Fibula (RMSE) and the accuracy of the three-dimensional positioning of the anatomic landmarks on the Femur and Tibia. The 3D model accuracy and the anatomical landmark positioning were evaluated comparing to the pre-defined success criteria. The data set for the 3D model accuracy included 67 pairs of a Knee X Ray and a CT scan of the same patient within a maximum

time frame of 6 months. Performance accuracy of the HealthJOINT software was compared to an established Ground Truth by an experienced US Board-Certified radiologist.

The HealthJOINT software performance accuracy was determined by measuring the RMSE (Root Mean Square Error), versus the ground truth. The HealthJOINT device performance for the Femur was an RMSE of 1.14 (95% CI: [1.097,1.187]), for the Tibia an RMSE of 1.05 (95% CI: [1.005,1.087]), and for the Fibula an RMSE of 0.94 (95% CI: [0.891, 0.986]). The device performance met the pre-defined success criteria.

Additionally, HealthJOINT performance accuracy in the identification of the anatomic landmark positioning versus the ground truth was determined by measuring the distance between the software landmarks positioning and the ground truth in mm, in terms of the standard deviation of the distance. The HealthJOINT software device precision met the performance goal. In conclusion, this study demonstrated the HealthJOINT safety and effectiveness and meets its intended use statement.

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 HealthJOINT 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: HealthJoint	Predicate Device: Efficient Care 3D Planning (K183544)	Summary
Intended Use/Indications for Use	The Zebra HealthJOINT device is a software tool for 3D reconstruction of bones from a set of 2D radiographs. The device is intended for assisting clinicians in the preoperative planning of knee orthopedic surgical procedures. Zebra's HealthJOINT analyzes cases using an artificial intelligence algorithm for the 3D model reconstruction. In addition to the model, the software provides a list of anatomical landmarks with their position on the 3D model. The result is made available via a 3rd parties' software interface for further display and analysis of the 3D bone model. Clinical judgement and experience are required to properly use the models produced by this software.	Efficient Care 3D Planning is software indicated for assisting orthopedic surgeons in preoperative planning of knee orthopedic surgeries. The software allows for the overlaying of 3D/2D implant models and for the visualization of the radiological images and 3D reconstruction of bones, and includes tools for performing measurements on the images or 3D model of bones, and for selecting and positioning the implant model. Clinical judgments and experience are required to properly use the software. Efficient Care 3D Planning is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPSFlex Gender, Persona® CR,	Similar. In addition to the 3D reconstruction and 3D/2D overlay for the visualization of radiological images, the predicate device also provide tools for performing measurements and for selecting the implant model.

		Persona PS, Vanguard® CR, and Vanguard PS.	
Classification/Product code	21 CFR 892.2050/LLZ	21 CFR 892.2050/LLZ	Same
User	Prespecified clinical users (clinicians)	Prespecified clinical users (clinicians)	Same
Radiological images format	DICOM	DICOM	Same
Modality	X-ray	X-ray	Same
Body part	Knee	Knee	Same
Software processing	Image segmentation and processing	Image segmentation and processing	Same
Output	3D bone reconstruction	3D bone reconstruction	Same
2D/3D Overlay	Yes	Yes	Same
Anatomic Landmarks	Yes	Yes	Same
Measurement Tools	No	Yes	Different, but do not raise questions of safety and effectiveness.
Implant Predictability	No	Yes	Different, but do not raise questions of safety and effectiveness.

Substantial Equivalence:

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, HealthJoint device raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety and effectiveness. The subject device has the same intended use, similar indications for use, and technological characteristics as the predicate device.

The results of the performance comparison study demonstrated that the HealthJoint device performs as intended, in the specified use conditions, and thus demonstrates the safety and effectiveness of the subject device.

The HealthJoint device is therefore substantially equivalent to the predicate device and share the same intended use and technological characteristics.