April 13, 2023

Ezra AI, Inc.
% David Girard
VP of Operations, Quality and Regulatory
419 Park Ave S, Suite 600
New York, NY 10016

Re: K230264
Trade/Device Name: Ezra Flash
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 6, 2023
Received: April 6, 2023

Dear David Girard:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230264

Device Name
Ezra Flash

Indications for Use *(Describe)*
Ezra Flash is an image processing software used for image enhancement of MR images. It can be used to reduce image noise in images acquired as part of non-contrast MRI exams on 3-Tesla Siemens and GE scanners for Sagittal T1, Axial T2 and Axial Flair sequences within the head region for patients > 18 years of age.

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.

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1 510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

1.1 Submitter Information

Submitter's Name	Ezra AI, Inc.
Address	419 Park Ave S, Suite 600, New York, NY 10016 USA
Telephone	+1 (646) 402-5751
Contact Person	David Girard
Date of Summary Preparation	January 31st, 2023

1.2 Subject Device Information

Device Name	Ezra Flash
Model Number	FLHAI00PL00IF00IT00LB00
Common Name	Ezra Flash
Classification	II
Review Panel	Radiology
Product Code	LLZ
Regulations	21 CFR 892.2050- System, Image Processing, Radiological

1.3 Predicate Device Information

Device Name	SubtleMR
510(k) Number	K203182

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2 Device Description

Ezra Flash is a Software as a Medical Device (SaMD) consisting of a software algorithm that enhances images of the head region taken by MRI scanners. As it only processes images for the end user, the device has no interface. It is intended to be used by radiologists in an imaging center, clinic, or hospital. The software can be used with MR images acquired as part of MRI exams on 3-Tesla Siemens and GE scanners.

The outputs are images with enhanced image quality. Both the original non-enhanced studies and the Ezra Flash-enhanced studies are available to the end user.

Ezra Flash receives DICOM-compliant non-contrast MR image inputs acquired on 3-Tesla scanners for Sagittal T1, Axial T2 and Axial Flair sequences within the head region. The software uses a convolutional neural network-based algorithm to improve image quality by reducing noise. The device outputs a DICOM-compliant copy of the images with improved image quality.

3 Indications for Use

Ezra Flash is an image processing software used for image enhancement of MR images. It can be used to reduce image noise in images acquired as part of non-contrast MRI exams on 3-Tesla Siemens and GE scanners for Sagittal T1, Axial T2 and Axial Flair sequences within the head region for patients $>$ 18 years of age.

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4 Summary of Technological Characteristics Comparison

Table 1 shows that Ezra Flash and the Predicate Device (K203182) are equivalent in technological characteristics.

Table 1: Subject and Predicate Device Comparison.

Feature	**Subject Device**	**Predicate Device (K203182)**
Regulation Number	CFR 892.2050	Same
Product Code	LLZ	Same
Indications for Use	Ezra Flash is an image processing software used for image enhancement of MR images. It can be used to reduce image noise for non-contrast 3T head MRI scans.	SubtleMR is an image processing software that can be used for image enhancement in MRI images. It can be used to reduce image noise for head, spine, neck, abdomen, pelvis, prostate, breast and musculoskeletal MRI, or increase image sharpness for head MRI.
Physical Characteristics	Software package that operates on off-the-shelf hardware	Same
Computer	Linux Compatible	Same
DICOM Standard Compliance	The software processes DICOM compliant image data	Same
Operating System	Linux	Same
Modalities	MRI	Same
User Interface	None – enhanced images are viewed on existing PACS workstations	Same

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Image Enhancement Algorithm Description	Ezra Flash software implements an image enhancement algorithm using a convolutional neural network-based filtering. Original images are enhanced by running through a cascade of filter banks, where thresholding and scaling operations are applied. These filters result in a single machine learning model that reduces noise. The parameters of the filters were obtained through an image-guided optimization process.	SubtleMR software implements an image enhancement algorithm using convolutional neural network based filtering. Original images are enhanced by running through a cascade of filter banks, where thresholding and scaling operations are applied. Separate neural network based filters are obtained for noise reduction and sharpness increase. The parameters of the filters were obtained through an image-guided optimization process.
Workflow	The software operates on DICOM files on the file system, enhances the images, and stores the enhanced images on the file system. The receipt of original DICOM image files and delivery of enhanced images as DICOM files depends on other software systems. Enhanced images co-exist with the original images.	Same

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5 Performance Testing

The Ezra Flash has been developed in a manner consistent with accepted standards for software development and evaluated in accordance with design specifications and applicable performance standards through software verification, validation, and usability testing.

Ezra performed the following main performance testing for Ezra Flash:

1. Signal-to-Noise Ratio (SNR)
    - SNR of a selected region of interest (ROI) in each test dataset is on average improved by $\geq$ 5% after Ezra Flash enhancement compared to original MR-acquired images (raw).
2. Contrast-to-Noise Ratio (CNR)
    - CNR of a selected region of interest (ROI) in each test dataset is on average improved by $>$ 0% after Ezra Flash enhancement compared to the MR-acquired raw images.
3. Image Quality - Perceived Noise
    - The mean Likert results for the Ezra Flash-enhanced images compared to the original MR-acquired images (raw) is greater than or equal to 0.5 Likert scale points.

The test results demonstrated that the Ezra Flash performs to its intended use, is deemed acceptable for clinical use, and does not introduce new questions of safety or efficacy. The testing was conducted in accordance to the software validation/verification plans and protocols. A full description of the software functionality, device hazard analysis, software requirements, verification, validation and usability study is provided in this submission.

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6 Conformance Standards

There are no applicable FDA mandated performance standards for this device. However, voluntary standards have been utilized in the production of the software. The device was designed and developed in accordance to the following conformance standards:

- ISO 14971:2019 - Medical Devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1: 2015 - Medical device software - Software life cycle processes
- NEMA PS 3.1-3.20 (2021e) - Digital Imaging and Communications in Medicine (DICOM) set

7 Substantial Equivalence Conclusion

The Ezra Flash has the same intended use and similar technological characteristics as the predicate SubtleMR (K203182) device. As demonstrated in this submission, the subject and predicate device are identical in indications for use and intended use for the reduction of image noise in 3T head MRI scans. The subject Ezra Flash is substantially equivalent to the predicate SubtleMR (K203182) device, and the minor differences in the technological characteristics of the subject and predicate device do not raise any new or different questions of safety and effectiveness.