



January 2, 2025

Ezra AI, Inc.
David Girard
Chief Operating Officer
419 Park Ave S, Suite 600
New York, New York 10016

Re: K242334
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: QIH
Dated: November 18, 2024
Received: November 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent 'FDA' watermark.

Daniel M. Krainak, Ph.D.
Assistant Director
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

Indications for Use

Submission Number (if known)

K242334

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 1.5-Tesla and 3-Tesla Siemens and GE scanners for patients > 18 years of age:

- Sagittal T1, Axial T2 and Axial Flair sequences within the head region
- Axial T2, Coronal T2 within the Abdomen region
- Sagittal T2, Axial T2, Coronal T2 within the Pelvis region

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	July 31st, 2024

1.2 Subject Device Information

Device Name	Ezra Flash
Model Number	FLHAI01PL02IF01IT01LB02
Common Name	Ezra Flash
Classification	II
Review Panel	Radiology
Product Code	QIH
Regulations	21 CFR 892.2050 System, Image Processing, Radiological

1.3 Predicate Device Information

Primary Predicate Device Name	Ezra Flash (Manufactured by Ezra AI, Inc.)
510(k) Number	K230264
Secondary Predicate Device Name	SubtleMR (Manufactured by Subtle Medical)
510(k) Number	K203182



2 Device Description

Ezra Flash is a Software as a Medical Device (SaMD) consisting of a software algorithm that enhances images of the head, abdomen, and pelvis regions 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 1.5-Tesla and 3-Tesla scanners from Siemens and GE.

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 1.5-Tesla and 3-Tesla scanners within the head, abdomen and pelvis regions. 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.

Ezra Flash is tested for performance on Sagittal T1, Axial T2, Axial T2 Flair images of the head, Coronal T2, Axial T2 images of the abdomen, Sagittal T2, Axial T2, and Coronal T2 images of the pelvis.

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 1.5-Tesla and 3-Tesla Siemens and GE scanners for patients > 18 years of age:

- Sagittal T1, Axial T2 and Axial Flair sequences within the head region
- Axial T2, Coronal T2 within the Abdomen region
- Sagittal T2, Axial T2, Coronal T2 within the Pelvis region



4 Summary of Technological Characteristics Comparison

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

Comparison of Technological Characteristics	Subject Device Ezra Flash	Primary Predicate (K230264)	Secondary Predicate (K203182)
Trade Name:	EzraFlash	EzraFlash	SubtleMR
Regulation Number:	21 CFR 892.2050	Same	Same
Product Code	QIH	LLZ	LLZ
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 1.5-Tesla and 3-Tesla Siemens and GE scanners for patients > 18 years of age: • Sagittal T1, Axial T2 and Axial Flair sequences within the head region • Axial T2, Coronal T2 within the Abdomen region • Sagittal T2, Axial T2, Coronal T2 within the Pelvis region	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.	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	Same



Computer	Linux Compatible	Same	Same
DICOM Standard Compliance	The software processes DICOM compliant image data	Same	Same
Operating System	Linux	Same	Same
Modalities	MRI	Same	Same
User Interface	None – enhanced images are viewed on existing PACS workstations	Same	Same
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. A dedicated machine-learning model is used for the head and body. The parameters of the filters were obtained through an image-guided optimization process.	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	Same
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Table 1: Subject and Predicate Device Comparison.



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 selected region of interests (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 selected region of interests (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.



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
- AAMI TIR57: 2016 - Principles For Medical Device Security - Risk Management

7 Substantial Equivalence Conclusion

The Ezra Flash has the same intended use and similar technological characteristics as the predicate Ezra Flash (K230264) and SubtleMR (K203182) device. The subject and predicate device are identical in indications for use and intended use for the reduction of image noise in 1.5T and 3T head, abdomen, and pelvis MRI scans. The subject Ezra Flash is substantially equivalent to the Ezra Flash (K230264) and 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.