Ezra AI Inc.
% Mr. David Girard
Quality Manager
79 Madison Ave., Ste 545
NEW YORK NY 10016

July 10, 2020

Re: K192969
Trade/Device Name: Ezra Plexo Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: June 9, 2020
Received: June 11, 2020

Dear Mr. 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,

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)*

K192969

Device Name
Ezra Plexo Software

Indications for Use *(Describe)*

Ezra Plexo Software is a medical diagnostic application for viewing, manipulation, 3D- visualization, and comparison of MR medical images. The images can be viewed in a number of output formats including volume rendering.

Ezra Plexo Software enables visualization of information that would otherwise have to be visually compared disjointedly.

Ezra Plexo Software is designed to support the oncological workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, and documentation of any such lesions.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. Ezra Plexo Software is a complement to these standard procedures.

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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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	79 Madison Avenue, Suite 545, New York, NY, 10016 USA
Telephone Number	888-402-3972
Contact Person	David Girard
Date of Summary Preparation	July 2, 2020

1.2 Subject Device Information

Device Name	Ezra Plexo Software
Common Name	Plexo
Classification	II
Review Panel	Radiology
Product Code	QIH
Regulations	892.2050 - Automated radiological image processing software

1.3 Predicate Device Information

Device Name	Arterys Oncology DL
510(k) Number	K173542

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2 Device Description

Ezra Plexo is a medical image application for 2D and 3D visualization, comparison, and manipulation of medical images. Plexo can be accessed through a web browser. It provides radiologists the ability to view and manipulate volumetric data such as MRI. The product allows volumetric segmentation of regions of interest, while enabling users to edit such segmentations and to take quantitative measurements.

Plexo does not interface directly with the MR scanner or any other data collection equipment. Instead, it uploads data files previously generated by such equipment. Its functionality is independent of the acquisition equipment vendor. Its analysis results are available on screen and can be saved for review.

3 Indications for Use

Ezra Plexo Software is a medical diagnostic application for viewing, manipulation, 3D-visualization, and comparison of medical MR images. The images can be viewed in a number of output formats including volume rendering.

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4 Summary of Technological Characteristics Comparison

Table 1 shows that Plexo Software and the Predicate Device (K173542) are equivalent in technological characteristics.

Feature	**Subject Device: Ezra Plexo Software**	**Predicate Device: Arterys Oncology DL (K173542)**
Platform	Chrome Desktop	Client-server, Chrome Desktop
DICOM Compliant	Yes	Yes
Type of Scans	MR	MR, CT
Image Navigation Tools	Pan, zoom, rotate, slice scroll (view multiple slices) Adjust window level, minimize/maximize Orientation labels, scroll sync, ruler	Pan, zoom, rotate, slice scroll (view multiple slices) Adjust window level, minimize/maximize Orientation labels, cross-reference indicator
Image Display Modes	Yes, static	Yes, static and cine
Text Annotation on the Image	Yes	Yes
Layout	Can select a viewport layout and add series to it	Can select a viewport layout and add series to it
2D Image Review	Yes	Yes
3D Image Review	Yes, 3D review of segmented region	Yes, 3D review of the full image
Create MPR Images	No	Yes
Manual Segmentation	Yes	Yes
2D Semi-Automated Segmentation	Yes, available only for MR prostate studies	Yes, available only for lung CT and liver MR studies
Linear Dimension Calculation	Yes	Yes
Volume Calculation	Yes	Yes

Table 1: Subject and Predicate Device Comparison

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5 Performance Testing

The Ezra Plexo Software 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.

The nonclinical software validation tests were performed on 150 patient exams utilizing consensus ground truth created by five U.S. board certified expert radiologists.

The test results demonstrated that the Ezra Plexo Software 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.

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 14971:2007- Medical devices - Application of risk management to medical devices
- IEC 62304:2006/A1:2015 - Medical device software - Software life cycle processes
- IEC 62366-1:2015 - Medical Devices - Application of usability engineering to medical devices
- NEMA PS 3.1-3.20 (2016) - Digital Imaging and Communications in Medicine (DICOM) set

7 Substantial Equivalence Conclusion

The Ezra Plexo Software has the same intended use and similar technological characteristics as the predicate Arterys Oncology DL (K173542) device. As demonstrated in this submission, the subject and predicate device are identical in indications for use and intended use. The subject Ezra Plexo Software is substantially equivalent to the predicate Arterys Oncology DL (K173542) 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.