February 26, 2025

Fovia, Inc.
Paula Brown
Head of Regulatory
P.O. Box 1858
Ross, California 94957

Re: K241546
Trade/Device Name: aiCockpit AI Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 24, 2025
Received: January 24, 2025

Dear Paula Brown:

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,

for

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241546

Device Name

aiCockpit AI Viewer

Indications for Use *(Describe)*

AI Viewer is software for clinical review intended for use in General Radiology and other healthcare imaging applications.

AI Viewer is intended to be used with off the shelf computing devices. AI Viewer supports major desktop browsers such as Microsoft Edge, Chrome, Safari.

AI Viewer can display annotations and measurements as an overlay on images from DICOM objects, and from AI software. The viewer can perform 3D Multi-Planar Reformatting (MPR), 3D Maximum Intensity Projection (MIP) and 3D Volume Rendering (VR). AI Viewer is purposed to aid in reviewing findings through its ability to display clinical documents and reports side by side with the images.

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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510(k) #: K241546

510(k) Summary

Prepared on: 2025-01-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fovia, Inc.
Applicant Address	P.O. Box 1858 Ross CA 94957 United States
Applicant Contact Telephone	415-328-3358
Applicant Contact	Ms. Paula Brown
Applicant Contact Email	paula.brown@fovia.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	aiCockpit AI Viewer
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222476	Ramsoft OmegaAI Image Viewer	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

AI Viewer is a stand-alone software as medical device (Stand-alone SaMD) for clinicians able to use web browsers at client stations to view DICOM image data. It is intended to provide image and related information to render and interact with AI findings and annotations from Lung Nodule detection AI algorithms, but it does not directly generate any potential findings or diagnosis.

AI Viewer allows trained medical professionals to perform 2D, MPR & 3D image manipulations using the Adjustment Tools, including window level, rotate, flip, pan, stack scroll, and magnify. AI Viewer is also capable of organizing all the images and presenting them in a zero-footprint, web user interface, allowing the users to view images in their preferred layout.

AI Viewer allows trained medical professionals to perform interactions with the AI Findings such as accept/reject/edit. Editing tools include selecting descriptive features for findings as well as allowing the physician to control editing quantifiable measurements first computed by AI such as lengths and volumes.

AI Viewer supports major desktop browsers such as Microsoft Edge, Chrome, Safari.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

AI Viewer is software for clinical review intended for use in General Radiology and other healthcare imaging applications.

AI Viewer is intended to be used with off the shelf computing devices. AI Viewer supports major desktop browsers such as Microsoft Edge, Chrome, Safari.

AI Viewer can display annotations and measurements as an overlay on images from DICOM objects, and from AI software. The viewer

can perform 3D Multi-Planar Reformatting (MPR), 3D Maximum Intensity Projection (MIP) and 3D Volume Rendering (VR). AI Viewer is purposed to aid in reviewing findings through its ability to display clinical documents and reports side by side with the images.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same

Technological Comparison 21 CFR 807.92(a)(6)

The Ramsoft OmegaAI Image Viewer is the predicate device for the Fovia AI Viewer. The two devices are substantially equivalent as they both provide the same functionality and possess the same technological characteristics.

From a high-level overview, both devices can "display annotations and measurements as an overlay on images from DICOM objects, and from AI software" (providing the same functionality) and both devices are based on the same architecture of "Server-based software solution that displays images and reports from a PACS using a zero-footprint application (browser)" (using the same technological characteristics).

From a more detailed level:
1. Both devices are intended for use in Radiology
2. Both devices are zero-footprint web-based JavaScript applications supporting common desktop browsers (e.g., Edge, Chrome, Safari)
3. Both devices display DICOM images
4. Both devices allow common image viewing tools such as Pan, Zoom, Window/Level, Rotate, & Scroll/Page
5. Both devices display annotations and measurement results from AI algorithms
6. Both devices allow the physician to control the editing and adjustment of the AI results (annotations and measurements)
7. Both devices provide flexible layout preferences

The only difference between the two devices is that Ramsoft OmegaAI Image Viewer provides more functionality than the Fovia AI Viewer - it could also be described as Fovia AI Viewer being a subset of the Ramsoft OmegaAI Image Viewer. For example:

1. Ramsoft OmegaAI Image Viewer supports images in a long list of -ology's (including radiology), while the Fovia AI Viewer is intended to be used only in radiology.
2. Ramsoft OmegaAI Image Viewer supports both Desktop Browser and Mobile environments while Fovia AI Viewer supports only Desktop Browser environments.
3. Ramsoft OmegaAI Image Viewer can be "used for image manipulation by radiology technologists (as well as radiologists for its other functionality)" while the Fovia AI Viewer is intended to be used by radiologists (for the same functionality at Ramsoft OmegaAI Image Viewer and not by radiology technologists at all).

Conclusion:
The comparison of the Subject Device with the predicate device shows that the aiCockpit AI Viewer software has similar functionality, intended use and technological characteristics as the predicate device. Based on the comparison to the predicate and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Software Validation and Verification Testing Summary

The performance data provided in the form of test cases as well as verification & validation test reports conducted on the AI Viewer include the following:

The verifications of features were performed by members of the QA team. The verification of the product AI Viewer has been performed with the following steps

• Full regression tests have been executed on the build with the implementations of all features. The purpose of this test phase is to uncover as much as possible all the potential bugs that could be detected by QA's test scripts.
• Bug fix verification for reported issues and regression test on related features
• End-to-end full tests have been executed on the candidate build for the release to verify all functionalities and fixes.

Not Applicable

Software Verification and Validation Testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices." In conclusion, the subject device is considered substantially equivalent to the predicate device