November 7, 2025

Imvaria, Inc.
% Dulciana Chan
Principal Consultant
RQM+
2790 Mosside Blvd
Monroeville, Pennsylvania 15146

Re: K252041
Trade/Device Name: Fibresolve (with PCCP)
Regulation Number: 21 CFR 892.2085
Regulation Name: Radiology Software For Referral Of Findings Related To Fibrotic Lung Disease
Regulatory Class: Class II
Product Code: QWO
Dated: October 10, 2025
Received: October 14, 2025

Dear Dulciana Chan:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Jessica Lamb, Ph.D.
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.*

510(k) Number *(if known)*
K252041

Device Name
Fibresolve (with PCCP)

Indications for Use *(Describe)*
Fibresolve is a software-only device that receives and analyzes lung computed tomography (CT) imaging data in order to provide a diagnostic subtype classification in suspected cases of interstitial lung disease (ILD). The device supplements the standard-of-care workflow by providing a qualitative, diagnostic classification output of imaging findings based on machine learning pattern recognition, in order to provide adjunctive information as part of a referral pathway to an appropriate Multidisciplinary Discussion (MDD) or as part of an MDD. Specifically, the tool is used to serve as an adjunct in the diagnosis of idiopathic pulmonary fibrosis (IPF) prior to invasive testing. The results of Fibresolve are intended to be used only by clinicians qualified in the care of lung disease, specifically in caring for patients with ILD, in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.

The input to Fibresolve must include a DICOM-compliant lung CT scan. Clinical case eligibility includes the following criteria:

- Age > 22 years old.
- Pulmonary symptoms suggestive of possible ILD including IPF.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

IMVARIA

# 510(k) Summary

# K252041 510(k) Summary

**DATE PREPARED**
November 7, 2025

**MANUFACTURER AND 510(k) OWNER**
IMVARIA, Inc.
2930 Domingo Ave #1496
Berkeley, CA 94705
Telephone: (650) 683-9800
Official Contact: Joshua Reicher, MD
CEO

**REPRESENTATIVE/CONSULTANT**
Dulciana D. Chan, MSE
RQM+
2790 Mosside Blvd
Monroeville, PA 15146
Telephone: +1 (412) 816-8253
Email: dchan@rqmplus.com

**DEVICE INFORMATION**

| | |
|---|---|
| Proprietary Name/Trade Name: | Fibresolve (with PCCP) |
| Common Name: | Radiology software for referral of findings related to fibrotic lung disease |
| Regulation Number: | 21 CFR 892.2085 |
| Class: | II |
| Product Code: | QWO |
| Review Panel: | Radiology |

**PREDICATE DEVICE IDENTIFICATION**
Fibresolve (with PCCP) is substantially equivalent to the following predicate:

| 510(k) Number | Device/Manufacturer | Predicate/Reference |
|---|---|---|
| DEN220040 | Fibresolve / Imvaria, Inc | Predicate |

**DEVICE DESCRIPTION**

Fibresolve is a software system developed for qualitative disease assessment of DICOM-compliant chest computed tomography (CT) imaging. The software system is based on a machine learning model component and a [Docker](https://docs.docker.com/get-docker/) based HTTP/1.1 Representational State Transfer (REST) software application programming interfaces (APIs) to enable image transfer, analysis, and output of results.

The device consists of the following 3 components: (1) Image Receiver API for image acquisition in the cloud; (2) Ingestion Pipeline and Analysis System for image processing and analysis; and (3) Output API for device output transmission.

(1) The Image Receiver API is accessed via any DICOM-compliant system (e.g. PACS). The hospital or clinic either accesses the API directly via secure software integration and submits the images electronically; or the images are transmitted manually (e.g. by mail) to the device manufacturer and the case is submitted to the device through the API directly by the manufacturer. The API passes the images to the Ingestion Pipeline and Analysis System (2).

(2) (a) The Ingestion Pipeline and (b) Analysis System accept the images, select cases appropriate for processing, process the images for analysis, and analyze the images. This Analysis System includes the Fibresolve Model Inference Graph that generates the assessment for the case. The final device output report data including identifying information and technical details about the case data and a binary result stating whether the data are determined to be suggestive for the target disease state.

- The Ingestion Pipeline identifies applicable CT imaging series from the case and verifies that the series is valid, completes quality checks, and confirms adequacy for analysis.
- The Fibresolve Model Inference Graph, the core component of the Analysis System, is an ensemble 3D deep learning model developed and trained using images from multiple facilities. Analysis System algorithm development phases included model pre-training, model training to the disease target, architecture optimization, threshold determination, and validation. No segmentation is performed as part of the Analysis System.

(3) The Output API transmits the Report data for the clinician to review. The Output API is either integrated into the hospital or clinic notification software (e.g. electronic health record) for electronic transmission or the device manufacturer transmits the Report in human-readable format directly (e.g. via fax). The clinician then incorporates the device Report as part of diagnostic decision-making.

The system does not include an image viewer or visual output for diagnostic use. The source images are reviewed for subjective assessment prior to submission to the device using the facility's standard diagnostic viewer as part of routine standard-of-care and the source images can be reassessed by the clinical team at any time before or after submission of the case to the device. The system only assesses for the target disease described in the Intended Use and does not replace imaging interpretation generally.

**INDICATIONS FOR USE**

Fibresolve is a software-only device that receives and analyzes lung computed tomography (CT) imaging data in order to provide a diagnostic subtype classification in suspected cases of interstitial lung disease (ILD). The device supplements the standard-of-care workflow by providing a qualitative, diagnostic classification output of imaging findings based on machine learning pattern recognition, in order to provide adjunctive information as part of a referral pathway to an appropriate Multidisciplinary Discussion (MDD) or as part of an MDD. Specifically, the tool is used to serve as an adjunct in the diagnosis of idiopathic pulmonary fibrosis (IPF) prior to invasive testing. The results of Fibresolve are intended to be used only by clinicians qualified in the care of lung disease, specifically in caring for patients with ILD, in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.

The input to Fibresolve must include a DICOM-compliant lung CT scan. Clinical case eligibility includes the following criteria:

- Age > 22 years old.
- Pulmonary symptoms suggestive of possible ILD including IPF.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

Fibresolve (with PCCP) includes an update to the original Fibresolve device to include a Predetermined Change Control Plan (PCCP) for the Fibresolve device, including an Algorithm Change Protocol (ACP) for the underlying Fibresolve Analysis Algorithm. The PCCP enables updates to the underlying Analysis Algorithm.

A table comparing the key features of the subject and predicate device is provided below.

| | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| | Fibresolve (with PCCP)<br>K252041 | Fibresolve<br>DEN220040 | - |
| Indications for Use | Fibresolve is a software-only device that receives and analyzes lung computed tomography (CT) imaging data in order to provide a diagnostic subtype classification in suspected cases of interstitial lung disease (ILD). The device supplements the standard-of-care workflow by providing a qualitative, diagnostic classification output of imaging findings based on machine learning pattern recognition, in order to provide adjunctive information as part of a referral pathway to an appropriate Multidisciplinary Discussion (MDD) or as part of an MDD. Specifically, the tool is used to serve as an adjunct in the diagnosis of idiopathic pulmonary fibrosis (IPF) prior to invasive testing. The results of Fibresolve are intended to be used only by clinicians qualified in the care of lung disease, specifically in caring for patients with ILD, in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.<br><br>The input to Fibresolve must include a DICOM-compliant lung CT scan. Clinical case eligibility includes the following criteria: | Fibresolve is a software-only device that receives and analyzes lung computed tomography (CT) imaging data in order to provide a diagnostic subtype classification in suspected cases of interstitial lung disease (ILD). The device supplements the standard-of-care workflow by providing a qualitative, diagnostic classification output of imaging findings based on machine learning pattern recognition, in order to provide adjunctive information as part of a referral pathway to an appropriate Multidisciplinary Discussion (MDD) or as part of an MDD. Specifically, the tool is used to serve as an adjunct in the diagnosis of idiopathic pulmonary fibrosis (IPF) prior to invasive testing. The results of Fibresolve are intended to be used only by clinicians qualified in the care of lung disease, specifically in caring for patients with ILD, in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.<br><br>The input to Fibresolve is a DICOM-compliant lung CT scan. Clinical case eligibility includes the following criteria: | Same |

| | | | |
|---|---|---|---|
| | Age > 22 years old.<br>Pulmonary symptoms suggestive of possible ILD including IPF. | Age > 22 years old.<br>Pulmonary symptoms suggestive of possible ILD including IPF. | |
| User population | Clinicians qualified in the care of lung disease, specifically in caring for patients with ILD | Clinicians qualified in the care of lung disease, specifically in caring for patients with ILD | Same |
| Target Population | Age > 22 years old. | Age > 22 years old. | Same |
| Anatomical region of interest | Chest | Chest | Same |
| Scan type and protocol | DICOM-compliant lung CT scan | DICOM-compliant lung CT scan | Same |
| Software Inputs | CT scan<br><br>Potentially age, sex, and pulmonary function tests (PFTs) | CT scan | Similar |
| Segmentation of region of interest | No; device does not mark, annotate, or direct users' attention to a specific location in the original image | No; device does not mark, annotate, or direct users' attention to a specific location in the original image | Same |
| Algorithm | Machine learning pattern recognition | Machine learning pattern recognition | Same |
| Alteration of original image | No | No | Same |
| Data Displayed | Qualitative classification output of imaging findings<br><br>Inputs that contribute to the diagnostic result | Qualitative classification output of imaging findings | Similar |

**SUMMARY OF NON-CLINICAL TESTING**

Software Verification and Validation (per IEC 62304) were performed to demonstrate safety based on current industry standards. The results of these tests indicate that the subject device is equivalent to the predicate device.

**PREDETERMINED CHANGE CONTROL PLAN**

Fibresolve includes a predetermined change control plan (PCCP), detailing the specific modifications (SaMD Pre-Specifications (SPS)) that may be made to the device and the specific methods in place to achieve and appropriately control the risks of the anticipated types of modifications (Algorithm Change Protocol (ACP)). The ACP outlines the process for data management, model re-training, performance evaluation, and update procedures associated with the change. The plan allows for modifications and updates to the underlying Analysis Algorithm within a limited scope of changes, specifically model architecture modification, introduction of new training data, and incorporation of ancillary inputs (while maintaining original inputs). Changes are evaluated via pre-specified statistical analyses in-line with those as part of the original device testing, to ensure, at minimum, non-inferior absolute performance, and potential improvements in performance, training data, or generalizability.

| Modification | Rationale | Testing Methods | Impact Assessment |
|---|---|---|---|
| Model architecture modification | With advancements in underlying model architecture through new computer science developments, new model training allows for improvements in performance in terms of overall metrics as well as consistency and speed. | Substantial equivalence as compared to the prior version. Statistical assessments following same standards used in original device clearance. | Revised generalizability or discriminatory capacity metrics for the system.<br><br>*Benefit-Risk Analysis:*<br>Benefit: Enhanced performance; generalizability.<br>Risk: Reduction in clinical performance or generalizability.<br><br>*Risk Mitigation:*<br>Evaluate device model on Test dataset metrics.<br>Execute unit and integration tests for the product code. |
| Introduction of new training data | With new training data, new model training allows for improvements in generalizability, robustness, and reductions in biases, which provides greater | Substantial equivalence as compared to the prior version. Statistical assessments following same standards used in original device | Revised sensitivity and specificity metrics for the system.<br><br>*Benefit-Risk Analysis:*<br>Benefit: Enhanced performance; generalizability. |

| | | | |
|---|---|---|---|
| | clinical value. Performance improvements may also be achieved. | clearance. | Risk: Reduction in clinical performance or generalizability.<br><br>*Risk Mitigation:*<br>Evaluate device model on Test dataset metrics.<br>Execute unit and integration tests for the product code. |
| Incorporation of ancillary inputs | Addition of non-imaging ancillary inputs into the model to improve overall performance with model component contributions displayed with the final result. improvements enhance performance and overall clinical value. | Substantial equivalence as compared to the prior version. Statistical assessments following same standards used in original device clearance | Revised sensitivity and specificity metrics for the system.<br><br>*Benefit-Risk Analysis:*<br>Benefit: Enhanced performance; generalizability; explainability.<br>Risk: Reduction in clinical performance or generalizability.<br><br>*Risk Mitigation:*<br>Evaluate device model on Test dataset metrics.<br>Execute unit and integration tests for the product code. |

**CONCLUSION**

The subject device and predicate devices are both intended to receive and analyze lung computed tomography (CT) imaging data to provide a diagnostic subtype classification in suspected cases of interstitial lung disease (ILD). Both devices supplement the standard-of-care workflow by providing a qualitative, diagnostic classification output of imaging findings based on machine learning pattern recognition, in order to provide adjunctive information as part of a referral pathway to an appropriate Multidisciplinary Discussion (MDD). Both devices are used to serve as an adjunct in the diagnosis of idiopathic pulmonary fibrosis (IPF) prior to invasive testing. The subject device incorporates a predetermined change control plan (PCCP) where changes are evaluated via pre-specified analyses to ensure non-inferior absolute performance ensuring the device performs as intended in the specified use conditions and does not present any new issues of safety or effectiveness. Thus, Fibresolve (with PCCP) is substantially equivalent to the predicate device.