Imbio, Inc.
William Mclain
QA/RA Manager
1015 Glenwood Avenue
Floor 4
Minneapolis, Minnesota 55405

December 19, 2024

Re: K242467
Trade/Device Name: IQ-UIP
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: November 18, 2024
Received: November 18, 2024

Dear William Mclain:

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,

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.

Submission Number *(if known)*

K242467

Device Name

IQ-UIP

Indications for Use *(Describe)*

Imbio IQ-UIP is a computer-aided software indicated for use in passively notifying specialists associated with interstitial lung disease (ILD) centers of radiological findings suggestive of radiological usual interstitial pneumonia (UIP) in non-contrast, chest CT scans of adults. Imbio IQ-UIP uses an artificial intelligence algorithm to analyze images and identify positive findings on a worklist application separate from and in parallel to the standard of care radiological image interpretation. Identification of positive findings include summary reports with a clinical guideline reference for the definition of UIP pattern that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of Imbio IQ-UIP are used to notify specialists at an ILD center of radiological findings that may be consistent with UIP. These specialists are qualified clinicians experienced in evaluating chest CTs for ILD. Input images originate from within the same hospital network associated with the ILD center. The results of Imbio IQ-UIP are intended to be used in conjunction with additional patient information and based on the user's professional judgment, to assist with the review of medical images. Notified clinicians are responsible for viewing full image series and making final clinical determinations.

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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K242467
510(k) Summary – IQ UIP

Submission Owner and Correspondent

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Date Summary Prepared

November 18, 2024

Device Trade Name

IQ-UIP

Device Common Name

Radiology Software For Referral Of Findings Related To Fibrotic Lung Disease

Device Classification Name

Radiology Software For Referral Of Findings Related To Fibrotic Lung Disease
21 CFR 892.2085
QWO

510(k) Summary – IQ UIP

Legally Marketed Device To Which The Device Is Substantially Equivalent

The IQ-UIP Software is substantially equivalent to the Imvaria, Inc Fibresolve authorized under DEN220040.

Description of the Device

Imbio IQ-UIP is a computer-aided software indicated for use in notifying specialists associated with Interstitial Lung Disease (ILD) Centers of radiological findings suggestive of radiological Usual Interstitial Pneumonia (UIP) in non-contrast, chest CT scans of adults.

Imbio IQ-UIP uses an artificial intelligence algorithm to analyze images and identify positive findings on a worklist application separate from and in parallel to the standard of care radiological image interpretation. Identification of positive findings include summary reports with a clinical guideline reference for the definition of UIP pattern that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The development of the deep learning inference model utilized anonymized, multi-center, retrospective, volumetric chest CT scans from several different, private and public data sources including multiple hospitals, clinical imaging centers, and imaging databases. Chest CT datasets were identified where each dataset represented an individual subject and acquisition. Data was subdivided into “bins” between the two stages of model development roughly 80%:20%: 1) model training and validation (i.e., hyper-parameter tuning) and 2) model testing (i.e. performance assessment). Site independence was maintained for several of the databases with clinical location data labels by randomly assigning each clinic location an integer value between 1 and 1000. Then, increasing from the lowest to highest random integer value, all data sets from a specific clinic location were assigned to the training bin until 80% of the total number of datasets from a database had been assigned to the training bin. The remaining were assigned to the testing bin. The testing data set was locked and quarantined from the datasets used in the device's model training and validation.

510(k) Summary – IQ UIP

The results of Imbio IQ-UIP are intended to be used in conjunction with other patient information and based on the user's professional judgment, to assist with the review of medical images. Notified clinicians are responsible for viewing full image series and making final clinical determinations.

Indication for Use

Imbio IQ-UIP is a computer-aided software indicated for use in passively notifying specialists associated with interstitial lung disease (ILD) centers of radiological findings suggestive of radiological usual interstitial pneumonia (UIP) in non-contrast, chest CT scans of adults. Imbio IQ-UIP uses an artificial intelligence algorithm to analyze images and identify positive findings on a worklist application separate from and in parallel to the standard of care radiological image interpretation. Identification of positive findings include summary reports with a clinical guideline reference for the definition of UIP pattern that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of Imbio IQ-UIP are used to notify specialists at an ILD center of radiological findings that may be consistent with UIP. These specialists are qualified clinicians experienced in evaluating chest CTs for ILD. Input images originate from within the same hospital network associated with the ILD center. The results of Imbio IQ-UIP are intended to be used in conjunction with additional patient information and based on the user's professional judgment, to assist with the review of medical images. Notified clinicians are responsible for viewing full image series and making final clinical determinations.

Technological Characteristics

The following table demonstrates the technical characteristics comparing the proposed to the predicate device.

Characteristic	Predicate: Fibresolve (DEN220040)	Proposed: IQ-UIP	Similarities or Differences
FDA Clearance	DEN220040	TBD	--
Clearance Date	01/12/2024	TBD	--
Product Code	QWO	QWO	Same

510(k) Summary – IQ UIP

Characteristic	Predicate: Fibresolve (DEN220040)	Proposed: IQ-UIP	Similarities or Differences
Class	II	II	Same
Regulation	892.2085	892.2085	Same
Software	Device is software only	Device is software only	Same
Software Documentation Level	Moderate	Basic	Documentation is similar and differences are due to updated FDA guidance.
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 is 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.	Imbio IQ-UIP is a computer-aided software indicated for use in passively notifying specialists associated with interstitial lung disease (ILD) centers of radiological findings suggestive of radiological usual interstitial pneumonia (UIP) in non-contrast, chest CT scans of adults. Imbio IQ-UIP uses an artificial intelligence algorithm to analyze images and identify positive findings on a worklist application separate from and in parallel to the standard of care radiological image interpretation. Identification of positive findings include summary reports with a clinical guideline reference for the definition of UIP pattern that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of Imbio IQ-UIP are used to notify specialists at an ILD center of radiological findings that may be consistent with UIP. These specialists are qualified clinicians experienced in evaluating chest CTs for ILD. Input images originate from within the same hospital network associated with the ILD center. The results of Imbio IQ-UIP are intended to be used in conjunction with additional patient information and based on the user's professional judgment, to assist with the review of medical	Similarities • Referral software for findings suggestive of a pre-specified clinical fibrotic lung condition • Uses artificial intelligence to analyze chest/lung CT images • Used by clinicians qualified in the care of lung disease • Operates in parallel to standard of care workflow • Provide qualitative diagnostic subtype classification for cases suspected of interstitial lung disease • Limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis

510(k) Summary – IQ UIP

Characteristic	Predicate: Fibresolve (DEN220040)	Proposed: IQ-UIP	Similarities or Differences
		images. Notified clinicians are responsible for viewing full image series and making final clinical determinations.	Differences: • IQ-UIP reports viewable on dedicated worklist application separate from standard-of-care.
Technical Method	The device supports referral of findings related to fibrotic lung diseases using machine learning, artificial intelligence or other image analysis algorithms.	The device supports referral of findings related to fibrotic lung diseases using machine learning, artificial intelligence or other image analysis algorithms.	Same
Target Area	The device operates on radiological images of the human body.	The device operates on radiological images of the human body.	Same
Anatomical Site	Lung/Chest	Lung/Chest	Same
Intended User Population	Clinicians qualified in care of lung disease	Clinicians qualified in care of lung disease	Same
Patient Population	Adults > 22 years old and with pulmonary symptoms suggestive of possible ILD including IPF.	Adults > 22 years old	Similarities: • Adults > 22 years old Differences: • Fibresolve's patient population is limited to those adults with pulmonary symptoms suggestive of possible ILD including IPF. • IQ-UIP patient population would include the same patient population as those indicated for Fibresolve but may also include others who have undergone a chest CT for other symptoms.
Communication with Patient	Does not communicate images to patients.	Does not communicate images to patients.	Same

510(k) Summary – IQ UIP

Characteristic	Predicate: Fibresolve (DEN220040)	Proposed: IQ-UIP	Similarities or Differences
Alteration of original image	No	No	Same
Viewing	Unknown	Referral report viewable on dedicated worklist application accessible by the intended users.	IQ-UIP reports viewable on dedicated worklist application separate from standard-of-care.

Software Validation

The IQ-UIP Software was subject to the following testing in association with software validation:

- Integration, Regression, and Algorithm Validation Testing
- Design Verification
- Unit Testing
- Standalone Performance Assessment

Summary Data

For primary endpoints, the device's AUC ROC is 96.6 [95.4, 97.7] and PPV is 77.9 [73.3, 82.8].

For secondary endpoints, the device's specificity is 91.5 [89.2, 93.7] and sensitivity is 90.2 [86.2, 94.3].

These data were collected from 804 individual patient images.

The prevalence of radiological UIP+ pattern in the standalone performance assessment cohort was 193/804 = 24.0%.

Positive and negative predictive values were estimated for various prevalences expected to be encountered by the device.

510(k) Summary – IQ UIP

Demographic data are presented in the following table.

Data Bin	Datasets	Percentage of Total (%)
Gender		
Male	437	54.4%
Female	300	37.3%
N/A	67	8.3%
Age (years)		
<50	89	11.1%
≥50 AND <60	150	18.7%
≥60 AND <70	257	32.0%
≥70 AND <80	215	26.7%
≥80	46	5.7%
N/A	47	5.8%
Race/Ethnicity		
White	302	37.6%
African-American	27	3.4%
Asian	21	2.6%
Hispanic	2	0.2%
American Indian or Alaska Native	2	0.2%
Native Hawaiian or Other Pacific Islander	1	0.1%
Other	1	0.1%
N/A	448	55.7%

510(k) Summary – IQ UIP

The following table describes clinical subgroups and cofounders present in the dataset.

Clinical Diagnosis	***Datasets (N)***
Emphysema	66
Idiopathic pulmonary fibrosis (Idiopathic UIP)	234
Nonspecific interstitial pneumonia (NSIP)	52
Pneumonia	115
Bronchiolitis	14
Uncharacterized ILD (uILD)	9
Cancer	2
Sarcoidosis	61
Hypersensitivity Pneumonitis (HP)	53
Connective Tissue Disease Related ILD (CTD-ILD)	53
Control	140
Other	5
Total	**804**

The following table describes equipment and protocols used to collect images.

Data Bin	**Datasets**	**Percentage of Total (%)**
Scanner Manufacturer		
GE Medical Systems	232	28.9%
Siemens	296	36.8%
Toshiba/Canon	89	11.1%
Philips	187	23.3%

"GE Equivalent" Reconstruction Kernel		
BONE (or equivalent)	14	1.7%
STANDARD (or equivalent)	433	53.9%
LUNG (or equivalent)	294	36.6%
SOFT (or equivalent)	63	7.8%
Slice Thickness (mm)		
<1.5	664	82.6%
≥1.5 AND <3	100	12.4%
=3	40	5.0%

Five experts, U.S. board-certified radiologists ("truthers") practicing within the United States performed ground truthing of the performance datasets. Each truther had a minimum of 5+ years experience evaluating chest CTs for ILDs and a clinical familiarity with using the ATS/ERS/JRS/ALAT diagnostic categories for UIP pattern. None of the enrolled truthers were involved in the development of the algorithm/device in any way, thus ensuring independence of testing and training data or other activities.

Biocompatibility

Biocompatibility testing is not applicable for the IQ-UIP.

Conclusions

The results of the comparison of design, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate device.