FDA 510(k) Premarket Notification

K252041 Fibresolve (with PCCP)

CLEARED

Nov 7, 2025
130 days to decision

K252041 · Product code: **QWO** · Radiology
Source: https://www.510kdatabase.net/k252041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiology Software For Referral Of Findings Related To Fibrotic Lung Disease. (QWO)
Date received	Jun 30, 2025
Decision date	Nov 7, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Imvaria, Inc.**
Location	Berkley, CA, US
Contact	Joshua Reicher
510(k) history	3 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Dulciana Chan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov