

**K252041 Fibresolve (with PCCP)**Nov 7, 2025  
130 days to decisionK252041 · Product code: **QWO** · Radiology  
Source: <https://www.510kdatabase.net/k252041/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Dulciana Chan

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252041/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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