

**K241847 Imbio PHA (4.0.0)**Aug 30, 2024  
65 days to decisionK241847 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k241847/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 26, 2024
Decision date	Aug 30, 2024
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imbio, Inc.</b>
Location	Minneapolis, MN, US
Contact	Lauren Keith
510(k) history	3 submissions · 3 cleared · 2023-2024

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