

**K252634 Imagine® Enterprise Suite**Jan 16, 2026  
149 days to decisionK252634 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k252634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 20, 2025
Decision date	Jan 16, 2026
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Softlink International Private Limited</b>
Location	Aundh, IN
Contact	Parkash S Kamat
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>I3cglobal Reghelps Pvt, Ltd.</b>
Contact	Sakthileela Nagaiyan

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

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