

**K251650 Insight Enhanced™ DRF (EN-1002-01)**Sep 16, 2025  
110 days to decisionK251650 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k251650/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	May 29, 2025
Decision date	Sep 16, 2025
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imaging Engineering, LLC</b>
Location	Cape Coral, FL, US
Contact	George Jachode
510(k) history	4 submissions · 4 cleared · 2019-2025

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