

**K210469 Insight Agile DRF**Jul 27, 2021  
161 days to decisionK210469 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k210469/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Feb 16, 2021
Decision date	Jul 27, 2021
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210469/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026