

K191310 Insight Essentials DRF Digital Imaging SystemJun 10, 2019
26 days to decisionK191310 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k191310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	May 15, 2019
Decision date	Jun 10, 2019
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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