

K200396 Insight Enhanced DRF Digital Imaging SystemMar 6, 2020
17 days to decisionK200396 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k200396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Feb 18, 2020
Decision date	Mar 6, 2020
Days to decision	17 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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