

K182834 CS-series-FP with Optional ROI Accessory CA-100SMar 29, 2019
171 days to decisionK182834 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k182834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Oct 9, 2018
Decision date	Mar 29, 2019
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Omega Medical Imaging, LLC
Location	Sanford, FL, US
Contact	John Newman Newman
510(k) history	7 submissions · 7 cleared · 2012-2025

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