

**K191713 CS-series-FP Radiographic / Fluoroscopic Systems  
with Optional CA-100S / FluoroShield™ (ROI Assembly)**Oct 4, 2019  
100 days to decisionK191713 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k191713/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jun 26, 2019
Decision date	Oct 4, 2019
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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