

**K191877 FLUOROspeed**Aug 5, 2019  
21 days to decisionK191877 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k191877/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jul 15, 2019
Decision date	Aug 5, 2019
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shimadzu Corporation</b>
Location	Kyoto, JP
Contact	Toshio Kadowaki
Website	<a href="http://www.shimadzu.com/">http://www.shimadzu.com/</a>
510(k) history	9 submissions · 9 cleared · 2014-2026

Shimadzu Corporation is a diversified manufacturer of analytical, measuring, and medical imaging instruments with a manufacturing facility in Kyoto, Japan. The company has operated for over 150 years, pioneering diagnostic imaging technologies and contributing to early disease detection and treatment worldwide. Shimadzu has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. The company's regulatory track record spans from 2014 to 2026, demonstrating sustained innovation in diagnostic imaging systems. Recent cleared de...

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