

**K233722 RADspeed Pro**Feb 23, 2024  
94 days to decisionK233722 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k233722/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 21, 2023
Decision date	Feb 23, 2024
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shimadzu Corporation</b>
Location	Kyoto, JP
Contact	Koichi Kataoka
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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k233722/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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