

K173517 RADspeed fitMar 30, 2018
136 days to decisionK173517 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k173517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 14, 2017
Decision date	Mar 30, 2018
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shimadzu Corporation
Location	Kyoto, JP
Contact	Toshio Kadowaki
Website	http://www.shimadzu.com/
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...
