

K123508 TRINIASFeb 26, 2014
470 days to decisionK123508 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k123508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 13, 2012
Decision date	Feb 26, 2014
Days to decision	470 days
Third-party review	No
Summary / Statement	Statement

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...
