FDA 510(k) Premarket Notification

K233719 FDR Visionary Suite

CLEARED

Mar 28, 2024
128 days to decision

K233719 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k233719/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 21, 2023
Decision date	Mar 28, 2024
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shimadzu Corporation**
Location	Kyoto, JP
Contact	Koichi Kataoka
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...

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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