FDA 510(k) Premarket Notification

K133580 ARTIS ONE

CLEARED

Apr 28, 2014
158 days to decision

K133580 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k133580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 21, 2013
Decision date	Apr 28, 2014
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	PATRICIA D JONES
510(k) history	778 submissions · 778 cleared · 1980-2026