FDA 510(k) Premarket Notification

K190768 ARTIS icono

CLEARED

Sep 12, 2019
170 days to decision

K190768 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k190768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Mar 26, 2019
Decision date	Sep 12, 2019
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	Patricia D. Jones
510(k) history	779 submissions · 779 cleared · 1980-2026