FDA 510(k) Premarket Notification

K062623 AXIOM LUMINOS DRF

CLEARED

Aug 22, 2007
351 days to decision

K062623 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k062623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 5, 2006
Decision date	Aug 22, 2007
Days to decision	351 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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