FDA 510(k) Premarket Notification

K050692 FLXIS

CLEARED

Apr 8, 2005
22 days to decision

K050692 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k050692/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Mar 17, 2005
Decision date	Apr 8, 2005
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems North America Co.**
Location	Shelton, CT, US
Contact	LYNN HARMER
510(k) history	24 submissions · 24 cleared · 2001-2010