FDA 510(k) Premarket Notification

K983877 PHILIPS INTEGRIS 3D RA OPTION

CLEARED

Dec 21, 1998
49 days to decision

K983877 · Product code: **IZI** · Radiology
Source: https://www.510kdatabase.net/k983877/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Nov 2, 1998
Decision date	Dec 21, 1998
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems North America, Inc.**
Location	Shelton, CT, US
Contact	PETER ALTMAN
510(k) history	71 submissions · 71 cleared · 1989-2010