K130318 NEXUS DRF DIGITAL X-RAY IMAGING SYSTEM (WITH PAXSCAN 4343CB)

CLEARED

Apr 22, 2013
73 days to decision

K130318 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k130318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Feb 8, 2013
Decision date	Apr 22, 2013
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Varian Medical Systems, X-Ray Products-Infimed**
Location	Liverpool, NY, US
Contact	CATHERINE MULCAHY
510(k) history	2 submissions · 2 cleared · 2013-2016