FDA 510(k) Premarket Notification

K101311 EP NAVIGATOR R3

CLEARED

Sep 30, 2010
142 days to decision

K101311 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k101311/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 11, 2010
Decision date	Sep 30, 2010
Days to decision	142 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