

K101311 EP NAVIGATOR R3Sep 30, 2010
142 days to decisionK101311 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101311/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026