

**K050692 FLXIS**Apr 8, 2005  
22 days to decisionK050692 · 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	<b>Philips Medical Systems North America Co.</b>
Location	Shelton, CT, US
Contact	LYNN HARMER
510(k) history	24 submissions · 24 cleared · 2001-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050692/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026