

K020055 PHILIPS INTEGRIS ALLURA 9 WITH FD OPTIONMar 15, 2002
66 days to decisionK020055 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k020055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jan 8, 2002
Decision date	Mar 15, 2002
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems
Location	Seattle, WA, US
Contact	LYNN HARMER
510(k) history	107 submissions · 105 cleared · 2002-2021

Philips Medical Systems is a Dutch multinational health technology company headquartered in Amsterdam with U.S. operations based in Seattle. The company evolved from a consumer electronics conglomerate founded in 1891 to a healthcare-focused organization. Philips Medical Systems has received FDA 510(k) clearances from total submissions between 2002 and 2021. The company's regulatory focus centered on Cardiovascular devices, which represented 79% of all submissions. This historical record reflects the company's significant presence in diagnostic ultrasound systems and pati...

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