

K100272 INTELLIVUE CLINICAL INFORMATION PORTFOLIOApr 14, 2010
75 days to decisionK100272 · Product code: **DXJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k100272/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Display, Cathode-ray Tube, Medical (DXJ)
Date received	Jan 29, 2010
Decision date	Apr 14, 2010
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems
Location	Seattle, WA, US
Contact	TERESA SCHMIDT
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...