

**K133603 PHILIPS CT DYNAMIC MYOCARDIAL PERFUSION
(DMP) APPLICATION**Sep 25, 2014
304 days to decisionK133603 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k133603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 25, 2013
Decision date	Sep 25, 2014
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems
Location	Seattle, WA, US
Contact	SUSAN QUICK
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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Device record: <https://www.510kdatabase.net/k133603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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