

**K183387 M3290B Patient Information Center iX**Aug 6, 2019  
243 days to decisionK183387 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k183387/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 6, 2018
Decision date	Aug 6, 2019
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems</b>
Location	Seattle, WA, US
Contact	Peng Cui
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...