FDA 510(k) Premarket Notification

CLEARED

K161164 CareEvent inclusive of the CareEvent Mobile Application accessory

Jun 24, 2016
60 days to decision

K161164 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k161164/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Apr 25, 2016
Decision date	Jun 24, 2016
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems**
Location	Seattle, WA, US
Contact	Theresa Poole
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...