K101521 ST/AR ST AND ARRHYTHMIA SOFTWARE MODEL: RELEASE K.O

CLEARED

Jul 29, 2010
57 days to decision

K101521 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k101521/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 2, 2010
Decision date	Jul 29, 2010
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems**
Location	Seattle, WA, US
Contact	LOIS GIEGERICH
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...