

**K023749 THE M3810A PHILIPS TELEMONITORING SYSTEM
WITH M3812B TELESTATION (M310A/12B)**Nov 19, 2002
11 days to decisionK023749 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k023749/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Nov 8, 2002
Decision date	Nov 19, 2002
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems
Location	Seattle, WA, US
Contact	J.P. OUELLETTE
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/k023749/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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