

K093177 INTELLIBRIDGE SYSTEMDec 18, 2009
71 days to decisionK093177 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k093177/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Oct 8, 2009 |
| Decision date | Dec 18, 2009 |
| Days to decision | 71 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------|
| Company | Philips Medical Systems |
| Location | Seattle, WA, US |
| Contact | CLAIRE ARAKAKI |
| 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...