

K181311 Philips Hemodynamic Application R1.0Sep 7, 2018
113 days to decisionK181311 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k181311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	May 17, 2018
Decision date	Sep 7, 2018
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Nederlands B.V.
Location	Best, NL
Contact	Owen Callaghan
510(k) history	8 submissions · 8 cleared · 2015-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181311/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 15, 2026