FDA 510(k) Premarket Notification

K181311 Philips Hemodynamic Application R1.0

CLEARED

Sep 7, 2018
113 days to decision

K181311 · 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