FDA 510(k) Premarket Notification

K211900 Patient Information Center iX

CLEARED

Mar 4, 2022
256 days to decision

K211900 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k211900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 21, 2021
Decision date	Mar 4, 2022
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medizin Systeme B?blingen GmbH**
Location	Boeblingen, DE
Contact	Peng Cui
510(k) history	8 submissions · 8 cleared · 2022-2025