FDA 510(k) Premarket Notification

K242962 Telemetry Monitor 5500 Release 4.0 (867232)

CLEARED

May 5, 2025
222 days to decision

K242962 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k242962/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 25, 2024
Decision date	May 5, 2025
Days to decision	222 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	Mary Couch
510(k) history	8 submissions · 8 cleared · 2022-2025