FDA 510(k) Premarket Notification

K241890 Philips Holter Analysis System

CLEARED

Mar 21, 2025
266 days to decision

K241890 · Product code: **MLO** · Cardiovascular
Source: https://www.510kdatabase.net/k241890/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Jun 28, 2024
Decision date	Mar 21, 2025
Days to decision	266 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	Cathy Hong
510(k) history	8 submissions · 8 cleared · 2022-2025