

K241890 Philips Holter Analysis SystemMar 21, 2025
266 days to decisionK241890 · Product code: **MLO** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241890/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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