FDA 510(k) Premarket Notification

K250569 Cardiologs Holter Platform

CLEARED

Aug 6, 2025
161 days to decision

K250569 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k250569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Feb 26, 2025
Decision date	Aug 6, 2025
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips France Commercial**
Location	Paris, FR
Contact	Sean Gibbons
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k250569/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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