

K212493 KODEX – EPD™ System 1.5.0Oct 24, 2022
441 days to decisionK212493 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k212493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 9, 2021
Decision date	Oct 24, 2022
Days to decision	441 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Nederland, B.V. (Pmsn)
Location	Best Noord-Brabant, NL
Contact	Betina Schepers
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212493/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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