FDA 510(k) Premarket Notification

K212493 KODEX – EPD™ System 1.5.0

CLEARED

Oct 24, 2022
441 days to decision

K212493 · 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