FDA 510(k) Premarket Notification

K233853 LumiGuide Wire

CLEARED

Mar 14, 2024
100 days to decision

K233853 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k233853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 5, 2023
Decision date	Mar 14, 2024
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	LumiGuide Equipment R2.0; LumiGuide 3D Hub

APPLICANT

Company	**Philips Medical Systems Nederland B.V.**
Location	Best, NL
Contact	Jeanette Becker
510(k) history	103 submissions · 102 cleared · 2005-2026