

K252645 LumiGuide Equipment R2.1Oct 24, 2025
64 days to decisionK252645 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k252645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 21, 2025
Decision date	Oct 24, 2025
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	LumiGuide Wire; 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252645/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026