

K211557 EndoPATxDec 29, 2022
589 days to decisionK211557 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k211557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 19, 2021
Decision date	Dec 29, 2022
Days to decision	589 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Itamar Medical , Ltd.
Location	Washington, DC, US
Contact	Moti Mikles
510(k) history	11 submissions · 11 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan Kahan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211557/> 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 24, 2026