FDA 510(k) Premarket Notification

K211557 EndoPATx

CLEARED

Dec 29, 2022
589 days to decision

K211557 · 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