

K243436 Seclusion CatheterFeb 28, 2025
115 days to decisionK243436 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k243436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Nov 5, 2024
Decision date	Feb 28, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Basis Medical
Location	Alpharetta, GA, US
Contact	David Martin
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Powers Regulatory Consulting
Contact	Grace Powers

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

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