FDA 510(k) Premarket Notification

K243436 Seclusion Catheter

CLEARED

Feb 28, 2025
115 days to decision

K243436 · 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