

**K231653 BASHIR™ .035 Endovascular Catheter, BASHIR™ S-B
.035 Endovascular Catheter**Jul 3, 2023
27 days to decisionK231653 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k231653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Jun 6, 2023
Decision date	Jul 3, 2023
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thrombolex, Inc.
Location	New Britain, PA, US
Contact	Amy Katsikas
510(k) history	6 submissions · 6 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Eminence Clinical Research, Inc.
Contact	Diane Horwitz

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/k231653/> 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 26, 2026