FDA 510(k) Premarket Notification

CLEARED

K231653 BASHIR™ .035 Endovascular Catheter, BASHIR™ S-B .035 Endovascular Catheter

Jul 3, 2023
27 days to decision

K231653 · 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