K222095 BASHIR Endovascular Catheter Ref. No. 7201, BASHIR S-B Endovascular Catheter, Ref. No. 7101

CLEARED

Apr 20, 2023
276 days to decision

K222095 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k222095/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Jul 18, 2022
Decision date	Apr 20, 2023
Days to decision	276 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

CLINICAL EVIDENCE - NCT04248868

tPA by Endovascular Administration for the Treatment of Submassive PE Using CDT for the Reduction of Thrombus Burden

Status	Completed
Enrollment	109 patients (actual)
Study sites	19 sites
Condition studied	Pulmonary Embolism
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 23, 2022
Sponsor	Thrombolex, Inc. (Industry)

Primary outcome

Efficacy: RV/LV Ratio Difference

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04248868