

**K211061 BASHIR Endovascular Catheter (Ref. 7201), BASHIR Plus 10 Endovascular Catheter (Ref. 7210), BASHIR Plus 20 Endovascular Catheter (Ref. 7220), BASHIR Plus 30 Endovascular Catheter (Ref. 7230), BASHIR Plus 40 Endovascular Catheter (Ref. 7240)**

Jun 10, 2021  
62 days to decision

K211061 · Product code: **QEY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211061/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Apr 9, 2021
Decision date	Jun 10, 2021
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Eminence Clinical Research, Inc.</b>
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)

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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k211061/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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