

K213166 Thrombuster II Aspiration CatheterOct 26, 2021
28 days to decisionK213166 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k213166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Sep 28, 2021
Decision date	Oct 26, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kaneka Medical America, LLC
Location	New York, NY, US
Contact	Audra Bogucki
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	KANEKA Corporation
Contact	Takeaki Miyata

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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