FDA 510(k) Premarket Notification

K213166 Thrombuster II Aspiration Catheter

CLEARED

Oct 26, 2021
28 days to decision

K213166 · 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