

K101839 KANEKA PHARMA AMERICA XPRESS-WAY RXOct 22, 2010
113 days to decisionK101839 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k101839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Jul 1, 2010
Decision date	Oct 22, 2010
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kaneka Pharma America, LLC
Location	Hudson, NH, US
Contact	RAYMOND KELLY
510(k) history	4 submissions · 4 cleared · 2010-2020

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