FDA 510(k) Premarket Notification

K121301 XPRESSWAY RX CATHETER (6F LD-VERISON)

CLEARED

Jul 30, 2012
90 days to decision

K121301 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k121301/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	May 1, 2012
Decision date	Jul 30, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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