FDA 510(k) Premarket Notification

K113363 ANGIOJET SOLENT DISTA THROMBECTOMY SET

CLEARED

Jun 6, 2012
204 days to decision

K113363 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k113363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Nov 15, 2011
Decision date	Jun 6, 2012
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medrad, Inc.**
Location	Mchenry, IL, US
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510(k) history	105 submissions · 105 cleared · 1976-2014