FDA 510(k) Premarket Notification

K130381 ANGIOJET ULTRA POWER PULSE KIT

CLEARED

Jul 29, 2013
165 days to decision

K130381 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k130381/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Feb 14, 2013
Decision date	Jul 29, 2013
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medrad, Inc.**
Location	Mchenry, IL, US
Contact	AMRA RACIC
Website	http://www.medrad.com/
510(k) history	105 submissions · 105 cleared · 1976-2014