FDA 510(k) Premarket Notification

K072769 ANGIOJET ULTRA

CLEARED

Nov 14, 2007
47 days to decision

K072769 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k072769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Sep 28, 2007
Decision date	Nov 14, 2007
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary
Other names	XMI (105041), XVG (105042) AND SPIROFLEX (106553) THROMBECTOMY SETS

APPLICANT

Company	**Possis Medical, Inc.**
Location	Walker, MI, US
Contact	MIKE BURNSIDE
510(k) history	34 submissions · 34 cleared · 1983-2014