FDA 510(k) Premarket Notification

CLEARED

K082382 ANGIOJET ULTRA AVX THROMBECTOMY SET, MODEL 105039

Dec 12, 2008
115 days to decision

K082382 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k082382/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Aug 19, 2008
Decision date	Dec 12, 2008
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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