FDA 510(k) Premarket Notification

K091703 HD GUIDE CATHETER, MODEL 90019, 90022, 90023, 90120, 90121, 90130, 90131

CLEARED

Oct 14, 2009
126 days to decision

K091703 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k091703/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Jun 10, 2009
Decision date	Oct 14, 2009
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Concentric Medical, Inc.**
Location	Moutian View, CA, US
Contact	KIRSTEN VALLEY
510(k) history	45 submissions · 44 cleared · 2001-2018