FDA 510(k) Premarket Notification

K041705 RESOLUTION THROMBECTOMY SYSTEM, MODEL EV-2

CLEARED

Sep 1, 2004
70 days to decision

K041705 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k041705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Jun 23, 2004
Decision date	Sep 1, 2004
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Omnisonics Medical Technologies**
Location	Wilmington, MA, US
Contact	ANNE M KULIS
510(k) history	8 submissions · 8 cleared · 1999-2008