FDA 510(k) Premarket Notification

K061772 TRIACTIV FX EMBOLIC PROTECTION SYSTEM

CLEARED

Jul 11, 2006
18 days to decision

K061772 · Product code: **NFA** · Cardiovascular
Source: https://www.510kdatabase.net/k061772/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Coronary Saphenous Vein Bypass Graft For Embolic Protection (NFA)
Date received	Jun 23, 2006
Decision date	Jul 11, 2006
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kensey Nash Corp.**
Location	Exton, PA, US
Contact	ROBIN M FATZINGER
510(k) history	19 submissions · 19 cleared · 1993-2011