FDA 510(k) Premarket Notification

K052523 PROXIS SYSTEM

CLEARED

Sep 7, 2006
358 days to decision

K052523 · Product code: **NFA** · Cardiovascular
Source: https://www.510kdatabase.net/k052523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Coronary Saphenous Vein Bypass Graft For Embolic Protection (NFA)
Date received	Sep 14, 2005
Decision date	Sep 7, 2006
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Velocimed, Inc.**
Location	Mineapolis, MN, US
Contact	KIMBERLY BRIGGS
510(k) history	5 submissions · 5 cleared · 2004-2006