FDA 510(k) Premarket Notification

K042117 PROXIS SYSTEM, MODEL EPS 101

CLEARED

Jan 7, 2005
155 days to decision

K042117 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k042117/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 5, 2004
Decision date	Jan 7, 2005
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k042117/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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