FDA 510(k) Premarket Notification

K092174 ENABLER-P CATHETER SYSTEM, MODEL 3000

CLEARED

Dec 30, 2009
162 days to decision

K092174 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k092174/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 21, 2009
Decision date	Dec 30, 2009
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Endocross, Ltd.**
Location	Washington, Dc, DC, US
Contact	JOHN SMITH
510(k) history	3 submissions · 3 cleared · 2008-2009