FDA 510(k) Premarket Notification

K130525 OCCLUSION PERFUSION CATHETER

CLEARED

Oct 3, 2013
217 days to decision

K130525 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k130525/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 28, 2013
Decision date	Oct 3, 2013
Days to decision	217 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Advanced Catheter Therapies, Inc.**
Location	Kenosha, WI, US
Contact	CHRIS HENZA
510(k) history	3 submissions · 3 cleared · 2013-2016