FDA 510(k) Premarket Notification

K070051 ACUMEN INSIGHT ENDOCARDIAL VISUALIZATION SYSTEM

CLEARED

Apr 6, 2007
92 days to decision

K070051 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k070051/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 4, 2007
Decision date	Apr 6, 2007
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acumen Medical, Inc.**
Location	Mountain View, CA, US
Contact	Marybeth Gamber
510(k) history	12 submissions · 12 cleared · 2004-2009