FDA 510(k) Premarket Notification

K110055 REVERSE MEDICAL REFLEX GUIDE CATHETER

CLEARED

Apr 5, 2011
85 days to decision

K110055 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k110055/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 10, 2011
Decision date	Apr 5, 2011
Days to decision	85 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Reverse Medical Corporation**
Location	Irvine, CA, US
Contact	AMY ESKINA
510(k) history	10 submissions · 10 cleared · 2009-2015