FDA 510(k) Premarket Notification

K042553 BIOCARDIA MORPH UNIVERSAL DEFLECTABLE GUIDE CATHETER

CLEARED

Feb 17, 2005
150 days to decision

K042553 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k042553/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 20, 2004
Decision date	Feb 17, 2005
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biocardia, Inc.**
Location	South San Francisco, CA, US
Contact	DANIEL C ROSENMAN
510(k) history	4 submissions · 4 cleared · 2002-2019