FDA 510(k) Premarket Notification

K113819 MONGOOSE ANGIOGRAPHIC CATHETER

CLEARED

Jul 11, 2012
197 days to decision

K113819 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k113819/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 27, 2011
Decision date	Jul 11, 2012
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pediacath, Inc.**
Location	Austin, TX, US
Contact	CAROLINE TONTINI
510(k) history	1 submissions · 1 cleared · 2012-2012