FDA 510(k) Premarket Notification

K180081 RAILWAY Sheathless Access System

CLEARED

Apr 18, 2018
97 days to decision

K180081 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k180081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 11, 2018
Decision date	Apr 18, 2018
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corporation**
Location	Warren, NJ, US
Contact	Michelle Ragozzino Rodgers
510(k) history	13 submissions · 12 cleared · 2004-2022