FDA 510(k) Premarket Notification

K152498 SoloPath Re-Collapsible Access System

CLEARED

Jan 5, 2016
126 days to decision

K152498 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k152498/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 1, 2015
Decision date	Jan 5, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Onset Medical Corporation**
Location	Mission Viejo, CA, US
Contact	Monika McDole-Russell
510(k) history	8 submissions · 8 cleared · 2005-2016