FDA 510(k) Premarket Notification

K162820 AC3 Series IABP System

CLEARED

Mar 31, 2017
175 days to decision

K162820 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k162820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Oct 7, 2016
Decision date	Mar 31, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arrow International, Inc.**
Location	Reading, PA, US
Contact	Alifiya Jagmag
510(k) history	19 submissions · 17 cleared · 2003-2020