FDA 510(k) Premarket Notification

K152161 Thoratec CentriMag Return (Arterial) Cannula Kit

CLEARED

Sep 18, 2015
46 days to decision

K152161 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k152161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Aug 3, 2015
Decision date	Sep 18, 2015
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Thoratec Corporation**
Location	Pleasnaton, CA, US
Contact	Lori DonDiego
Website	http://www.thoratec.com/
510(k) history	2 submissions · 2 cleared · 2015-2015