FDA 510(k) Premarket Notification

CLEARED

K112565 NOVAPORT ONE VASCULAR ACCESS CANNULA

Dec 6, 2011
95 days to decision

K112565 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k112565/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Sep 2, 2011
Decision date	Dec 6, 2011
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Novalung GmbH**
Location	North Attleboro, MA, US
Contact	Leann Christman
510(k) history	2 submissions · 2 cleared · 2007-2011