FDA 510(k) Premarket Notification

K141465 CARDIOGARD EMBOLI PROTECTION CANNULA

CLEARED

Jan 9, 2015
220 days to decision

K141465 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k141465/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jun 3, 2014
Decision date	Jan 9, 2015
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiogard Medical, Ltd.**
Location	Amherst, MA, US
Contact	SHEILA H HEYER
510(k) history	2 submissions · 2 cleared · 2015-2019