

K182302 CardioGard Emboli Protection CannulaMay 17, 2019
266 days to decisionK182302 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k182302/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Aug 24, 2018
Decision date	May 17, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiogard Medical, Ltd.
Location	Amherst, MA, US
Contact	Orit Ronan
510(k) history	2 submissions · 2 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	Heyer Regulatory Solutions, LLC
Contact	Sheila Hemeon-Heyer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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