

**K062429 MODIFICATION TO EMBOL-X INTRA-AORTIC FILTER:
X-SMALL, SMALL, MEDIUM, LARGE, X-LARGE WITH HEPARIN
COATED MESH**Sep 27, 2006
37 days to decisionK062429 · Product code: **DTM** · Cardiovascular
Source: <https://www.510kdatabase.net/k062429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Aug 21, 2006
Decision date	Sep 27, 2006
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences Research Medical
Location	Midvale, UT, US
Contact	KAREN JONES
510(k) history	6 submissions · 6 cleared · 1998-2008

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