

K082321 TERUMO ROCSAFE HYBRID PERFUSION SYSTEMFeb 13, 2009
184 days to decisionK082321 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k082321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Aug 13, 2008
Decision date	Feb 13, 2009
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Cardiovascular Systems Corp.
Location	Elkton, MD, US
Contact	GARY A COURTNEY
510(k) history	43 submissions · 43 cleared · 2000-2015

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