

**K012209 CAPIOX SP PUMP WITH X-COATING PRODUCT CODE:
CXSP45X**Aug 15, 2001
30 days to decisionK012209 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k012209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jul 16, 2001
Decision date	Aug 15, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012209/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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