

K200091 Capiox iCP Centrifugal PumpNov 18, 2021
672 days to decisionK200091 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k200091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jan 16, 2020
Decision date	Nov 18, 2021
Days to decision	672 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Terumo Cardiovascular Systems Corporation
Location	Elkton, MD, US
Contact	John Chesney
510(k) history	29 submissions · 29 cleared · 2002-2024

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