

**K991864 ROTAFLOW CENTRIFUGAL PUMP SYSTEM**Aug 31, 2000  
457 days to decisionK991864 · Product code: **KFM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k991864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jun 1, 1999
Decision date	Aug 31, 2000
Days to decision	457 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jostra Medizintechnik AG</b>
Location	Newark, DE, US
Contact	KATHY JOHNSON
510(k) history	2 submissions · 2 cleared · 2000-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991864/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026