

**K083794 MECC SET WITH BIOLINE COATING**Apr 21, 2009  
120 days to decisionK083794 · Product code: **KFM** · CardiovascularSource: <https://www.510kdatabase.net/k083794/>**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	Dec 22, 2008
Decision date	Apr 21, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maquet Cardiopulmonary, AG</b>
Location	Fairfield, IA, US
Contact	KATRIN SCHWENKLENKS
510(k) history	44 submissions · 44 cleared · 2005-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083794/> 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 4, 2026