

**K170029 FloPump 32mL, Sterile, FloPump 32mL, Non-Sterile**Dec 15, 2017  
345 days to decisionK170029 · Product code: **KFM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k170029/>**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	Jan 4, 2017
Decision date	Dec 15, 2017
Days to decision	345 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>International Biophysics Corporation</b>
Location	Austin, TX, US
Contact	Geoff Marcek
510(k) history	3 submissions · 3 cleared · 2013-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170029/> 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 May 27, 2026