

**K031300 IBC FLOPUMP WITH GBS COATING**May 14, 2003  
20 days to decisionK031300 · Product code: **KFM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k031300/>**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	Apr 24, 2003
Decision date	May 14, 2003
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gish Biomedical, Inc.</b>
Location	Mchenry, IL, US
Contact	J. HARVEY KNAUSS
510(k) history	75 submissions · 75 cleared · 1983-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031300/> 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 26, 2026