

K193663 FloPump 57mL Centrifugal PumpMar 10, 2021
435 days to decisionK193663 · Product code: **KFM** · CardiovascularSource: <https://www.510kdatabase.net/k193663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Dec 31, 2019
Decision date	Mar 10, 2021
Days to decision	435 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193663/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026