

K832594 PRE-BYPASS FILTER #EC-PBF SERIESSep 20, 1983
49 days to decisionK832594 · Product code: **KRJ** · CardiovascularSource: <https://www.510kdatabase.net/k832594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Prebypass, Cardiopulmonary Bypass (KRJ)
Date received	Aug 2, 1983
Decision date	Sep 20, 1983
Days to decision	49 days
Third-party review	No

APPLICANT

Company	Gish Biomedical, Inc.
Location	Mchenry, IL, US
510(k) history	75 submissions · 75 cleared · 1983-2009

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k832594/> 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 26, 2026