

K895435 FRESENIUS AS 104 CELL SEPARATORNov 2, 1990
421 days to decisionK895435 · Product code: **LKN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k895435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Sep 7, 1989
Decision date	Nov 2, 1990
Days to decision	421 days
Third-party review	No

APPLICANT

Company	Fresenius USA, Inc.
Location	Walker, MI, US
Contact	GARRY J VIBERT
510(k) history	38 submissions · 37 cleared · 1984-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895435/>; 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 25, 2026