

**K961706 P1R PLASMA TREATMENT SET FOR USE IN  
PLASMAPHERESIS WITH THE FRESENIUS AS104 CELL  
SEPARATOR**Jul 31, 1996  
90 days to decisionK961706 · Product code: **LKN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k961706/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	May 2, 1996
Decision date	Jul 31, 1996
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius USA, Inc.</b>
Location	Walker, MI, US
Contact	TOM FOLDEN
510(k) history	38 submissions · 37 cleared · 1984-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961706/>; 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 25, 2026