

K122952 NIPRO PUREFLUX-L HEMODIALYZERDec 4, 2013
435 days to decisionK122952 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k122952/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Sep 25, 2012
Decision date	Dec 4, 2013
Days to decision	435 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nipro Medical Corporation
Location	Lexington, KY, US
Contact	CAROLYN GEAORGE
510(k) history	34 submissions · 34 cleared · 2005-2026

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