

K160444 FB-U HemodialyzerFeb 8, 2017
357 days to decisionK160444 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 17, 2016
Decision date	Feb 8, 2017
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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