

K182940 Surdial DX Hemodialysis SystemJul 19, 2019
269 days to decisionK182940 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 23, 2018
Decision date	Jul 19, 2019
Days to decision	269 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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