FDA 510(k) Premarket Notification

K131935 ELISIO-H HEMODIALYZER, ELISIO-M HEMODIALYZER

CLEARED

Dec 20, 2013
176 days to decision

K131935 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k131935/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 27, 2013
Decision date	Dec 20, 2013
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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