

**K953996 NIKKISO CO, LTD., FLX10GW, 12GW, 15GW, 18GW & 21GW HEMODIALYZERS**

Mar 19, 1997  
573 days to decision

K953996 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k953996/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 24, 1995
Decision date	Mar 19, 1997
Days to decision	573 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>NIKKISO CO., LTD.</b>
Location	Mchenry, IL, US
Contact	JEFFERY R SHIDERMAN
510(k) history	11 submissions · 11 cleared · 1981-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k953996/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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