

**K002512 TORAYSULFONE DIALYZER**Oct 15, 2001  
426 days to decisionK002512 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k002512/>**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 15, 2000
Decision date	Oct 15, 2001
Days to decision	426 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Toray Industries (America), Inc.</b>
Location	New York, NY, US
Contact	LISA S JONES
510(k) history	18 submissions · 18 cleared · 1986-2004

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