

**K883407 TORAY FILTRYZER BK SERIES**Feb 27, 1989  
200 days to decisionK883407 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k883407/>**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 11, 1988
Decision date	Feb 27, 1989
Days to decision	200 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883407/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026