

**K061519 MODIFICATION TO DBB-05 HEMODIALYSIS DELIVERY SYSTEM**

Sep 28, 2007  
484 days to decision

K061519 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k061519/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 1, 2006
Decision date	Sep 28, 2007
Days to decision	484 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>NIKKISO CO., LTD.</b>
Location	Mchenry, IL, US
Contact	FUMIAKI KANAI
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/k061519/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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