

**K043461 CUSTODIOL**Feb 28, 2005  
75 days to decisionK043461 · Product code: **KDL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k043461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Perfusion, Kidney, Disposable (KDL)
Date received	Dec 15, 2004
Decision date	Feb 28, 2005
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dr. Franz Kohler Chemie GmbH</b>
Location	Brookeville, MD, US
Contact	T. WHIT ATHEY
510(k) history	5 submissions · 5 cleared · 1999-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043461/> 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 21, 2026