

K080650 OMNI-DL SYSTEMNov 26, 2008
264 days to decisionK080650 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k080650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 7, 2008
Decision date	Nov 26, 2008
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Transvivo, Inc.
Location	Richmond, CA, US
Contact	J. MICHAEL DELMAGE
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080650/> Data sourced from FDA 510(k) public records (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. - Generated June 24, 2026