FDA 510(k) Premarket Notification

CLEARED

K093379 TCX-I-DV REMOTE CARE MANAGEMENT SYSTEM

Feb 9, 2010
103 days to decision

K093379 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 29, 2009
Decision date	Feb 9, 2010
Days to decision	103 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**BI Healthcare, Inc.**
Location	Foxboro, MA, US
Contact	MICHAEL MATHUR
510(k) history	5 submissions · 5 cleared · 2005-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k093379/ 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 15, 2026