

K113493 TCX-I REMOTE CARE MANAGEMENT SYSTEMDec 21, 2011
26 days to decisionK113493 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k113493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Nov 25, 2011
Decision date	Dec 21, 2011
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113493/> 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