K101331 LABSYSTEM PRO EP RECORDING SYSTEM V3.1 SOFTWARE

CLEARED

Oct 8, 2010
150 days to decision

K101331 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k101331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 11, 2010
Decision date	Oct 8, 2010
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard Inc., Bard Electrophysiology Division**
Location	Lowell, MA, US
Contact	ANASTASIA C RANDALL
510(k) history	3 submissions · 3 cleared · 2008-2012