K092181 HEMOSIL ACUSTAR CARDIOLIPIN IGG, IGM AND IGG AND IGM CONTROLS

CLEARED

Mar 11, 2010
233 days to decision

K092181 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k092181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jul 21, 2009
Decision date	Mar 11, 2010
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Instrumentation Laboratory CO**
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023