FDA 510(k) Premarket Notification

CLEARED

K012053 DIAMEDIX IS-ANTI-CARDIOLIPIN SCREEN TEST SYSTEM

Aug 20, 2001
49 days to decision

K012053 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k012053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jul 2, 2001
Decision date	Aug 20, 2001
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diamedix Corp.**
Location	Miami, FL, US
Contact	LYNNE STIRLING
510(k) history	68 submissions · 68 cleared · 1986-2011