FDA 510(k) Premarket Notification

K001875 DIAMEDIX IS-RUBELLA IGM CAPTURE TEST SYSTEM

CLEARED

Aug 21, 2000
62 days to decision

K001875 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k001875/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jun 20, 2000
Decision date	Aug 21, 2000
Days to decision	62 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