FDA 510(k) Premarket Notification

CLEARED

K932373 HEMAGEN CARDIOLIPIN ANTIBODY KIT (EIA METHOD0

Jul 16, 1993
60 days to decision

K932373 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k932373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	May 17, 1993
Decision date	Jul 16, 1993
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hemagen Diagnostics, Inc.**
Location	Waltham, MA, US
Contact	CHARLES A WILLAND
Website	http://www.hemagen.com/
510(k) history	52 submissions · 52 cleared · 1986-2004

Hemagen Diagnostics, Inc. was founded in 1985 by scientists from Boston University School of Medicine. The company provides clinical diagnostic solutions specializing in immunology devices for autoimmune and infectious disease testing. Hemagen offers gold standard IFA products, ELISA, HA, and point-of-care testing formats for human and veterinary diagnostics. Hemagen has received FDA 510(k) clearances from total submissions since its first clearance in 1986. The company's regulatory portfolio focuses on immunology devices, including antibody detection kits, autoimmune scr...