

K941840 HEMAGEN ACL IGA CALIBRATORJun 30, 1994
78 days to decisionK941840 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k941840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Apr 13, 1994
Decision date	Jun 30, 1994
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hemagen Diagnostics, Inc.
Location	Waltham, MA, US
Contact	JOSEPH M CALIFANO
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...
