

K946123 HEMAGEN ENA SM KIT (EIA METHOD)Feb 22, 1995
69 days to decisionK946123 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k946123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Dec 15, 1994
Decision date	Feb 22, 1995
Days to decision	69 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...
