FDA 510(k) Premarket Notification

CLEARED

K950414 HEMAGEN ENA SM/RMP KIT (EIA METHOD)

Mar 29, 1995
57 days to decision

K950414 · Product code: **LLL** · Immunology
Source: https://www.510kdatabase.net/k950414/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jan 31, 1995
Decision date	Mar 29, 1995
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hemagen Diagnostics, Inc.**
Location	Waltham, MA, US
Contact	JOSEPH MCALIFANO
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...