FDA 510(k) Premarket Notification

K973823 PR 3 ANTIBODY KIT

CLEARED

Nov 13, 1997
37 days to decision

K973823 · Product code: **MOB** · Immunology
Source: https://www.510kdatabase.net/k973823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Oct 7, 1997
Decision date	Nov 13, 1997
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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