

K972812 RAICHEM PREALBUMIN SPIAAug 28, 1997
31 days to decisionK972812 · Product code: **DDS** · Immunology
Source: <https://www.510kdatabase.net/k972812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prealbumin, Fitc, Antigen, Antiserum, Control (DDS)
Date received	Jul 28, 1997
Decision date	Aug 28, 1997
Days to decision	31 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...
