

**K971909 VIRGO AMA ELISA KIT**Jun 20, 1997  
28 days to decisionK971909 · Product code: **DBM** · Immunology  
Source: <https://www.510kdatabase.net/k971909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	May 23, 1997
Decision date	Jun 20, 1997
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemagen Diagnostics, Inc.</b>
Location	Waltham, MA, US
Contact	JOSEPH M CALIFANO
Website	<a href="http://www.hemagen.com/">http://www.hemagen.com/</a>
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...

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