

K992241 VIRGO B2 GLYCOPROTEIN I IGA ANTIBODY KITAug 30, 1999
60 days to decisionK992241 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k992241/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV) |
| Date received | Jul 1, 1999 |
| Decision date | Aug 30, 1999 |
| Days to decision | 60 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...
