

K031101 RAICHEM ASSAYED CONTROL SERUM LEVEL 1 & 2Jun 16, 2003
70 days to decisionK031101 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k031101/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Apr 7, 2003 |
| Decision date | Jun 16, 2003 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Hemagen Diagnostics, Inc. |
| Location | Waltham, MA, US |
| Contact | JOSE MONTANEZ |
| 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...
