

**K920927 KEMTROL SERUM CONTROL-NORMAL CAT NO. 7024**Jun 19, 1992  
112 days to decisionK920927 · Product code: **JJY** · Chemistry  
Source: <https://www.510kdatabase.net/k920927/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Feb 28, 1992
Decision date	Jun 19, 1992
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k920927/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026