

**K040925 NORMAL AND HYPERGAMMA CONTROL SERUM**Apr 28, 2004  
20 days to decisionK040925 · Product code: **JJY** · Immunology  
Source: <https://www.510kdatabase.net/k040925/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Apr 8, 2004
Decision date	Apr 28, 2004
Days to decision	20 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sebia</b>
Location	Chelsea, MI, US
Contact	BOREK JANIK
Website	<a href="http://www.sebia.com/">http://www.sebia.com/</a>
510(k) history	32 submissions · 32 cleared · 1995-2024

Sebia is a global specialized in vitro diagnostic (IVD) player providing powerful diagnostic tools for chronic and metabolic diseases. The company operates with a manufacturing facility in Chelsea, US, and serves laboratories worldwide with instruments, tests, and software solutions. Sebia has received FDA 510(k) clearances from total submissions since 1995, with no denied submissions on record. The company specializes in immunology devices, including capillary electrophoresis and immunofixation technologies. Latest clearance in 2024 confirms active regulatory engagement....

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