

**K970477 HYRAGEL ISO-LDH KIT/HYDRAGEL 15 ISO-LDH KIT**Mar 10, 1997  
31 days to decisionK970477 · Product code: **CFE** · Chemistry  
Source: <https://www.510kdatabase.net/k970477/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Lactate Dehydrogenase Isoenzymes (CFE)
Date received	Feb 7, 1997
Decision date	Mar 10, 1997
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sebia</b>
Location	Chelsea, MI, US
Contact	BOREK JANIK, PH.D.
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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