

K951536 HYDRAGEL PROTEIN(E) KITJun 30, 1995
88 days to decisionK951536 · Product code: **CEF** · Chemistry
Source: <https://www.510kdatabase.net/k951536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Protein Fractionation (CEF)
Date received	Apr 3, 1995
Decision date	Jun 30, 1995
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sebia
Location	Chelsea, MI, US
Contact	BOREK JANIK
Website	http://www.sebia.com/
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....
