

K190851 HYDRASHIFT 2/4 daratumumabMay 2, 2019
30 days to decisionK190851 · Product code: **CFF** · Immunology
Source: <https://www.510kdatabase.net/k190851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunoelectrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Apr 2, 2019
Decision date	May 2, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sebia
Location	Chelsea, MI, US
Contact	Karen Anderson
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....
