FDA 510(k) Premarket Notification

K172195 HYDRASHIFT 2/4 daratumumab, daratumumab Control

CLEARED

Jan 11, 2018
174 days to decision

K172195 · Product code: **CFF** · Immunology
Source: https://www.510kdatabase.net/k172195/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoelectrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Jul 21, 2017
Decision date	Jan 11, 2018
Days to decision	174 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....