FDA 510(k) Premarket Notification

CLEARED

K210623 FLC Kappa, FLC Lambda, FLC Control Level 1, FLC Control Level 2

Nov 18, 2022
626 days to decision

K210623 · Product code: **DFH** · Immunology
Source: https://www.510kdatabase.net/k210623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Mar 2, 2021
Decision date	Nov 18, 2022
Days to decision	626 days
Third-party review	No
Combination product	No
PCCP authorized	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....