FDA 510(k) Premarket Notification

K180762 CAPI 3 HEMOGLOBIN(E)

CLEARED

Dec 14, 2018
266 days to decision

K180762 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k180762/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Mar 23, 2018
Decision date	Dec 14, 2018
Days to decision	266 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....