

K232027 CAPI 3 NEONAT Hb, CAPILLARYS 3 DBS InstrumentApr 4, 2024
272 days to decisionK232027 · Product code: **GKA** · Hematology
Source: <https://www.510kdatabase.net/k232027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Jul 7, 2023
Decision date	Apr 4, 2024
Days to decision	272 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....

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Device record: <https://www.510kdatabase.net/k232027/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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