FDA 510(k) Premarket Notification

K082227 MINICAP HEMOGLOBIN(E) KIT, MODEL 2207, 2227

CLEARED

Mar 26, 2009
231 days to decision

K082227 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k082227/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Aug 7, 2008
Decision date	Mar 26, 2009
Days to decision	231 days
Third-party review	No
Summary / Statement	Statement

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....