FDA 510(k) Premarket Notification

CLEARED

K162281 CAPI 3 Hb A1c, MULTI-SYSTEM Hb A1C CAPILLARY CONTROLS (2)

Feb 17, 2017
186 days to decision

K162281 · Product code: **LCP** · Chemistry
Source: https://www.510kdatabase.net/k162281/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Aug 15, 2016
Decision date	Feb 17, 2017
Days to decision	186 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....