FDA 510(k) Premarket Notification

K171537 CAPI 3 Hb A1c

CLEARED

Sep 12, 2017
110 days to decision

K171537 · Product code: **PDJ** · Chemistry
Source: https://www.510kdatabase.net/k171537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	May 25, 2017
Decision date	Sep 12, 2017
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sebia**
Location	Chelsea, MI, US
Contact	Karen Aderson
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....