FDA 510(k) Premarket Notification

K100307 GELSCAN, MODEL 1206

CLEARED

Aug 31, 2010
209 days to decision

K100307 · Product code: **CFE** · Chemistry
Source: https://www.510kdatabase.net/k100307/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Lactate Dehydrogenase Isoenzymes (CFE)
Date received	Feb 3, 2010
Decision date	Aug 31, 2010
Days to decision	209 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....