FDA 510(k) Premarket Notification

CLEARED

K022053 HYDRAGEL 7 LIPOPROTEIN(E), PN 4114 & HYDRAGEL LIPOPROTEIN(E) 15/30 PN 4134

Jul 12, 2002
18 days to decision

K022053 · Product code: **JHO** · Chemistry
Source: https://www.510kdatabase.net/k022053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrophoretic Separation, Lipoproteins (JHO)
Date received	Jun 24, 2002
Decision date	Jul 12, 2002
Days to decision	18 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sebia**
Location	Chelsea, MI, US
Contact	BOREK JANIK
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....