

K063498 HYDRAGEL 18 A1AT ISOFOCUSING KIT (PN 4356)Jun 11, 2007
203 days to decisionK063498 · Product code: **OBZ** · Immunology
Source: <https://www.510kdatabase.net/k063498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin Kit, Qualitative Phenotype (OBZ)
Date received	Nov 20, 2006
Decision date	Jun 11, 2007
Days to decision	203 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....
