

K011113 HYDRAGEL ISO-PAL K20 (PN 3022)Jun 13, 2001
63 days to decisionK011113 · Product code: **CIN** · Chemistry
Source: <https://www.510kdatabase.net/k011113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Alkaline Phosphatase Isoenzymes (CIN)
Date received	Apr 11, 2001
Decision date	Jun 13, 2001
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement
Other names	HYDRAGEL 7 ISO-PAL (PN 4112); HYDRAGEL 15 ISO-PAL (PN 4132)

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....
