

**K042939 CAPILLARY&apos;S IMMUNOTYPING (PN 2100)**Jun 27, 2005  
245 days to decisionK042939 · Product code: **DFH** · Immunology  
Source: <https://www.510kdatabase.net/k042939/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Oct 25, 2004
Decision date	Jun 27, 2005
Days to decision	245 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sebia, Inc.</b>
Location	Chelsea, MI, US
Contact	BOREK JANIK
510(k) history	2 submissions · 2 cleared · 2005-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042939/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 26, 2026