

**K052291 CAPILLARY'S HEMOGLOBIN(E) (PN 2007)**Jun 27, 2006  
308 days to decisionK052291 · Product code: **GKA** · Hematology  
Source: <https://www.510kdatabase.net/k052291/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Abnormal Hemoglobin Quantitation (GKA) |
| Date received         | Aug 23, 2005                           |
| Decision date         | Jun 27, 2006                           |
| Days to decision      | 308 days                               |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sebia</b>  |
| Location       | Chelsea, MI, US   |
| Contact        | KAREN ANDERSON  |
| Website        | <a href="http://www.sebia.com/">http://www.sebia.com/</a> |
| 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....

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