

**K981048 HYDRAGEL 6 CSF KIT**Oct 7, 1998  
201 days to decisionK981048 · Product code: **CFF** · Immunology  
Source: <https://www.510kdatabase.net/k981048/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | Immunoelectrophoretic, Immunoglobulins, (g, A, M) (CFF) |
| Date received         | Mar 20, 1998  |
| Decision date         | Oct 7, 1998   |
| Days to decision      | 201 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Morax</b>                            |
| Location       | Chelsea, MI, US                         |
| Contact        | BOREK JANIK, PH.D.                      |
| 510(k) history | 12 submissions · 12 cleared · 1996-2003 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981048/> 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 28, 2026