

**K990250 HYDRAGEL LDL/HDL CHOL DIRECT KIT-P.N. 4005,  
HYDRAGEL 7 LDL/HDL CHOL DIRECT KIT-P.N. 4103,  
HYDRAGEL LDL/HDL CHOL DIRECT 0**Jun 18, 1999  
143 days to decisionK990250 · Product code: **LBT** · Chemistry  
Source: <https://www.510kdatabase.net/k990250/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Traditional  |
| Device classification | Electrophoresis, Cholesterol Via Esterase-oxidase, Hdl (LBT) |
| Date received         | Jan 26, 1999   |
| Decision date         | Jun 18, 1999   |
| Days to decision      | 143 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Morax</b>                            |
| Location       | Chelsea, MI, US                         |
| Contact        | BOREK JANIK                             |
| 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/k990250/> 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