

**K984303 VITROS CHEMISTRY PRODUCTS MAGNETIC HDL-  
CHOLESTEROL REAGENT**Jan 28, 1999  
57 days to decisionK984303 · Product code: LBR · Chemistry  
Source: <https://www.510kdatabase.net/k984303/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Ldl & Vldl Precipitation, Hdl (LBR) |
| Date received         | Dec 2, 1998                         |
| Decision date         | Jan 28, 1999                        |
| Days to decision      | 57 days                             |
| Third-party review    | No                                  |
| Summary / Statement   | Statement                           |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ortho-Clinical Diagnostics, Inc.</b>   |
| Location       | Rochester, NY, US                         |
| Contact        | MARLENE SHULMAN                           |
| 510(k) history | 106 submissions · 104 cleared · 1997-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984303/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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