

**K032932 DIRECT HDL-CHOLESTEROL LIQUID COLOR**Mar 10, 2004  
170 days to decisionK032932 · Product code: **LBS** · Chemistry  
Source: <https://www.510kdatabase.net/k032932/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS) |
| Date received         | Sep 22, 2003  |
| Decision date         | Mar 10, 2004  |
| Days to decision      | 170 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |
| Other names           | DIRECT HDL/LDL-CHOLESTEROL CALIBRATOR                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Stanbio Laboratory</b>               |
| Location       | Mchenry, IL, US                         |
| Contact        | ADAObI OGUCHI                           |
| 510(k) history | 47 submissions · 47 cleared · 1977-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032932/> 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 23, 2026