

**K033674 MULTIGENT HEMOGLOBIN A1C (REAGENTS), HB A1C CALIBRATORS AND HB A1C CONTROLS**Feb 9, 2004  
77 days to decisionK033674 · Product code: LCP · Chemistry  
Source: <https://www.510kdatabase.net/k033674/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Assay, Glycosylated Hemoglobin (LCP) |
| Date received         | Nov 24, 2003                         |
| Decision date         | Feb 9, 2004                          |
| Days to decision      | 77 days                              |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Seradyn, Inc.</b>                    |
| Location       | Indianapolis, IN, US                    |
| Contact        | LES PADILLA                             |
| 510(k) history | 28 submissions · 28 cleared · 1988-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033674/>; 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