

**K143504 IMMULITE 2000 Albumin Calibration Verification  
Material, IMMULITE 2000 Myoglobin Calibration Verification  
Material**Jan 14, 2015  
35 days to decisionK143504 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k143504/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received         | Dec 10, 2014  |
| Decision date         | Jan 14, 2015  |
| Days to decision      | 35 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Siemens Healthcare Diagnostics, Inc.</b>   |
| Location       | New York, NY, US  |
| Contact        | Sara Kastrup  |
| Website        | <a href="https://www.siemens-healthineers.com">https://www.siemens-healthineers.com</a> |
| 510(k) history | 152 submissions · 151 cleared · 2008-2026   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143504/> 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 May 14, 2026