

K161526 LIAISON CMV IgM Serum Control SetJun 30, 2016
28 days to decisionK161526 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k161526/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Jun 2, 2016 |
| Decision date | Jun 30, 2016 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | DiaSorin, Inc. |
| Location | Ellicott City, MD, US |
| Contact | JOHN WALTER |
| 510(k) history | 70 submissions · 69 cleared · 1998-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161526/> Data sourced from FDA 510(k) public records (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. - Generated June 2, 2026