

K072794 IMMULITE 2500 OM-MA, MODEL L5KOPNov 5, 2007
35 days to decisionK072794 · Product code: **LTK** · Immunology
Source: <https://www.510kdatabase.net/k072794/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK) |
| Date received | Oct 1, 2007 |
| Decision date | Nov 5, 2007 |
| Days to decision | 35 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Siemens Medical Solutions Diagnostics |
| Location | New York, NY, US |
| Contact | MAYA MAHUE-GIANGRECO |
| 510(k) history | 11 submissions · 11 cleared · 2007-2011 |

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