

**K010878 MODIFICATION TO IMMULITE HERPES I & II IGG,
MODEL L2KHS2 & L2KHS6**Apr 18, 2001
30 days to decisionK010878 · Product code: **LGC** · Microbiology
Source: <https://www.510kdatabase.net/k010878/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC) |
| Date received | Mar 19, 2001 |
| Decision date | Apr 18, 2001 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Products Corp. |
| Location | Mchenry, IL, US |
| Contact | EDWARD M LEVINE |
| 510(k) history | 321 submissions · 321 cleared · 1976-2006 |

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