

K961109 ACTIVE LH IRMAApr 5, 1996
16 days to decisionK961109 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k961109/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Luteinizing Hormone (CEP) |
| Date received | Mar 20, 1996 |
| Decision date | Apr 5, 1996 |
| Days to decision | 16 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Diagnostic Systems Laboratories, Inc. |
| Location | Mchenry, IL, US |
| Contact | JOHN WILLIS |
| 510(k) history | 94 submissions · 94 cleared · 1981-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961109/> 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 29, 2026