

K891095 VIS-DISK HCG (EIA) LYOPHILIZED JPL-044MJun 16, 1989
106 days to decisionK891095 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k891095/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Human Chorionic Gonadotropin (DHA) |
| Date received | Mar 2, 1989 |
| Decision date | Jun 16, 1989 |
| Days to decision | 106 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Leeco Diagnostics, Inc. |
| Location | Mchenry, IL, US |
| Contact | DANTE J CAPALDI,PHD |
| 510(k) history | 49 submissions · 49 cleared · 1979-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k891095/>; 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