

K850928 V.E.P. HIP -VARIABLE ENDO-PROSTHESISMay 28, 1985
84 days to decisionK850928 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k850928/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal (KWL) |
| Date received | Mar 5, 1985 |
| Decision date | May 28, 1985 |
| Days to decision | 84 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Unitas Ent. |
| Location | San Francisco, CA, US |
| Contact | MICHAEL M STEK |
| 510(k) history | 1 submissions · 1 cleared · 1985-1985 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k850928/>; 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 May 22, 2026