

K971813 EMBLAJan 16, 1998
245 days to decisionK971813 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k971813/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Standard Polysomnograph With Electroencephalograph (OLV) |
| Date received | May 16, 1997 |
| Decision date | Jan 16, 1998 |
| Days to decision | 245 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ferguson Medical |
| Location | Chico, CA, US |
| Contact | FRANK FERGUSON |
| 510(k) history | 57 submissions · 55 cleared · 1985-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971813/> 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 18, 2026