

K991025 LUMA-CATH FIXED CURVE EP CATHETERSOct 15, 1999
200 days to decisionK991025 · Product code: **DRF** · CardiovascularSource: <https://www.510kdatabase.net/k991025/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF) |
| Date received | Mar 29, 1999 |
| Decision date | Oct 15, 1999 |
| Days to decision | 200 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Irvine Biomedical, Inc. |
| Location | Irvine, CA, US |
| Contact | ROGER TU |
| 510(k) history | 11 submissions · 11 cleared · 1995-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991025/> 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 24, 2026