

K875015 TRACETS 3000Jan 28, 1988
55 days to decisionK875015 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k875015/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Electrocardiograph (DRX) |
| Date received | Dec 4, 1987 |
| Decision date | Jan 28, 1988 |
| Days to decision | 55 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Lectec Corp. |
| Location | Mchenry, IL, US |
| Contact | DAVID MONTECALVO |
| 510(k) history | 27 submissions · 26 cleared · 1977-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k875015/>; 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 20, 2026