

K862655 SIGNA II RESTING ECG ELECTRODEAug 6, 1986
23 days to decisionK862655 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k862655/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Electrocardiograph (DRX) |
| Date received | Jul 14, 1986 |
| Decision date | Aug 6, 1986 |
| Days to decision | 23 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Kone Instruments, Inc. |
| Location | Mchenry, IL, US |
| Contact | FRANCIS I DOMINY |
| 510(k) history | 12 submissions · 12 cleared · 1982-1987 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k862655/>; 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 July 3, 2026