

K893393 EPO-TRAC BY RADIOIMMUNOASSAY (RIA)Nov 21, 1989
204 days to decisionK893393 · Product code: **GGT** · Chemistry
Source: <https://www.510kdatabase.net/k893393/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Assay, Erythropoietin (GGT) |
| Date received | May 1, 1989 |
| Decision date | Nov 21, 1989 |
| Days to decision | 204 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Incstar Corp. |
| Location | Stillwater, MN, US |
| Contact | G TALLAS |
| 510(k) history | 58 submissions · 57 cleared · 1987-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893393/>; 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 29, 2026