

K892528 FIVE-YEAR STERILE PACKAGING SHELF LIFEJan 18, 1990
282 days to decisionK892528 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k892528/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received | Apr 11, 1989 |
| Decision date | Jan 18, 1990 |
| Days to decision | 282 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Daig Corp. |
| Location | Mchenry, IL, US |
| Contact | JOHN FLEISCHHACKER |
| 510(k) history | 63 submissions · 63 cleared · 1977-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k892528/>; 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