

K812245 INTERMEDICS POLY FLEX ENDOCARDIAL ATRIALOct 6, 1981
56 days to decisionK812245 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k812245/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received | Aug 11, 1981 |
| Decision date | Oct 6, 1981 |
| Days to decision | 56 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Intermedics, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 211 submissions · 201 cleared · 1977-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k812245/> 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 28, 2026