

K790100 ISOLATION SLEEVE, MODEL 348-01Jan 24, 1979
8 days to decisionK790100 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k790100/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Jan 16, 1979 |
| Decision date | Jan 24, 1979 |
| Days to decision | 8 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k790100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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