

K833199 SILICONE RUBBER ISOLATION SLEEVE 350-01Oct 28, 1983
39 days to decisionK833199 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k833199/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Sep 19, 1983 |
| Decision date | Oct 28, 1983 |
| Days to decision | 39 days |
| Third-party review | No |

APPLICANT

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

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