

K790101 ISOLATION SLEEVE, MODEL 346-01Jan 24, 1979
8 days to decisionK790101 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k790101/>**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

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Device record: <https://www.510kdatabase.net/k790101/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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