

K863418 MODEL 352-01 SILICONE RUBBER ISOLATION SLEEVESep 24, 1986
21 days to decisionK863418 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k863418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Sep 3, 1986
Decision date	Sep 24, 1986
Days to decision	21 days
Third-party review	No

APPLICANT

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

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