

K911122 8MM QUANTUM PULSE/SUPRIMA II PULSE GENERATORSMay 16, 1991
65 days to decisionK911122 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k911122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 12, 1991
Decision date	May 16, 1991
Days to decision	65 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911122/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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