

**K851365 SORIN BIOMEDICA ORION 30/A CARDIAC
STIMULATOR & PM**Dec 3, 1985
242 days to decisionK851365 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k851365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 5, 1985
Decision date	Dec 3, 1985
Days to decision	242 days
Third-party review	No

APPLICANT

Company	Sorin Biomedica, Fiat, USA, Inc.
Location	Mchenry, IL, US
Contact	JEANNE-MARIE VARGA
510(k) history	20 submissions · 20 cleared · 1980-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k851365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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