

K801647 SONACOLOR 6100Aug 20, 1980
33 days to decisionK801647 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k801647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 18, 1980
Decision date	Aug 20, 1980
Days to decision	33 days
Third-party review	No

APPLICANT

Company	Carolina Medical Electronics
Location	Mchenry, IL, US
510(k) history	11 submissions · 11 cleared · 1977-1991

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Device record: <https://www.510kdatabase.net/k801647/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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