

K800645 CYBERLITH IMPLANTABLE PULSE GEN. #253-04Apr 8, 1980
15 days to decisionK800645 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k800645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 24, 1980
Decision date	Apr 8, 1980
Days to decision	15 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k800645/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 28, 2026