

K792216 ARCOLITH 2100-CARDIAC PULSE GENERATORNov 29, 1979
24 days to decisionK792216 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k792216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 5, 1979
Decision date	Nov 29, 1979
Days to decision	24 days
Third-party review	No

APPLICANT

Company	Arco Medical Products Co.
Location	Walker, MI, US
510(k) history	21 submissions · 20 cleared · 1976-1980

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k792216/> 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 July 9, 2026