

K801806 EXTERNAL SILASTIC BOOT FOR CARDIAC PULSESep 9, 1980
41 days to decisionK801806 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k801806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 30, 1980
Decision date	Sep 9, 1980
Days to decision	41 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k801806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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