

K800286 CRITERION II PACING SYSTEM MONITORSMar 12, 1980
33 days to decisionK800286 · Product code: **DTC** · Cardiovascular
Source: <https://www.510kdatabase.net/k800286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function (DTC)
Date received	Feb 8, 1980
Decision date	Mar 12, 1980
Days to decision	33 days
Third-party review	No

APPLICANT

Company	Dart Medical Equipment
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1980-1982

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Device record: <https://www.510kdatabase.net/k800286/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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