

K781144 ANALYZER, PACER SYSTEM, PSA-5Aug 23, 1978
44 days to decisionK781144 · Product code: **DTC** · Cardiovascular
Source: <https://www.510kdatabase.net/k781144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function (DTC)
Date received	Jul 10, 1978
Decision date	Aug 23, 1978
Days to decision	44 days
Third-party review	No

APPLICANT

Company	Edwards Pacemaker Systems
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1977-1979

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Device record: <https://www.510kdatabase.net/k781144/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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