

K801978 PROGRAMALITH #'S 221, 222, 221A & 222ASep 26, 1980
38 days to decisionK801978 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k801978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 19, 1980
Decision date	Sep 26, 1980
Days to decision	38 days
Third-party review	No

APPLICANT

Company	Pacesetter Systems
Location	Mchenry, IL, US
510(k) history	96 submissions · 96 cleared · 1976-1991

Pacesetter Systems was a biotechnology company founded by Alfred E. Mann in 1965, headquartered in McHenry, US. The company pioneered implantable medical devices, including the first commercial rechargeable implantable pacemaker and early telemetry-enabled systems. Pacesetter Systems received FDA 510(k) clearances from total submissions between 1976 and 1991. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. This historical record reflects the company's core expertise in pacemaker technology, leads, adapters, and ...