FDA 510(k) Premarket Notification

K810582 ELECTRODE, PACEMAKER PERMANENT

CLEARED

Mar 13, 1981
10 days to decision

K810582 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k810582/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Mar 3, 1981
Decision date	Mar 13, 1981
Days to decision	10 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 ...