

**K843703 PERMATHANE 865 & 867 UNIPOLAR POLYURETH**Jan 8, 1985  
109 days to decisionK843703 · Product code: **DTD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k843703/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker Lead Adaptor (DTD)
Date received	Sep 21, 1984
Decision date	Jan 8, 1985
Days to decision	109 days
Third-party review	No

**APPLICANT**

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Company	<b>Pacesetter Systems</b>
Location	Mchenry, IL, US
Contact	NES KUSNIERZ
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 ...

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