FDA 510(k) Premarket Notification

K830016 VASCUTEK VASCULAR PROTHESIS VP1200K/50K

CLEARED

Dec 21, 1983
352 days to decision

K830016 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k830016/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jan 3, 1983
Decision date	Dec 21, 1983
Days to decision	352 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 ...