FDA 510(k) Premarket Notification

K883750 VENTRALITH I

CLEARED

Jan 13, 1989
134 days to decision

K883750 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k883750/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Sep 1, 1988
Decision date	Jan 13, 1989
Days to decision	134 days
Third-party review	No

APPLICANT

Company	**Bio Pace Technology, Inc.**
Location	Butler, PA, US
Contact	K SETHI
510(k) history	1 submissions · 1 cleared · 1989-1989