FDA 510(k) Premarket Notification

K812464 SYNTHEMED PULSE GENERATOR VVI MODEL 1000

CLEARED

Nov 16, 1981
77 days to decision

K812464 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k812464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 31, 1981
Decision date	Nov 16, 1981
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**Synthemed Corp.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1981-1981