FDA 510(k) Premarket Notification

K894240 NEOS 02

CLEARED

Oct 26, 1989
128 days to decision

K894240 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k894240/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 20, 1989
Decision date	Oct 26, 1989
Days to decision	128 days
Third-party review	No

APPLICANT

Company	**Biotronik Cardiac Pacemakers**
Location	Lake Oswego, CA, US
Contact	RICHARD STOUT
510(k) history	3 submissions · 3 cleared · 1989-1990