FDA 510(k) Premarket Notification

K905087 TRIOS 02

CLEARED

May 7, 1991
175 days to decision

K905087 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k905087/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 13, 1990
Decision date	May 7, 1991
Days to decision	175 days
Third-party review	No

APPLICANT

Company	**Biotronik, GmbH & Co.**
Location	Lake Oswego, OR, US
Contact	RICHARD R STOUT
510(k) history	18 submissions · 17 cleared · 1989-2000