FDA 510(k) Premarket Notification

K941937 PIKOS E 01-B

CLEARED

Aug 30, 1994
131 days to decision

K941937 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k941937/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SP
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 21, 1994
Decision date	Aug 30, 1994
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotronik, Inc.**
Location	Lake Oswego, OR, US
Contact	LAUREN L FOOTE CHRISTENSEN
Website	https://www.biotronik.com
510(k) history	85 submissions · 67 cleared · 1994-2026

Biotronik, Inc. designs and manufactures advanced active implants for cardiac rhythm management, monitoring, and electrophysiology. The company operates with a manufacturing facility in Lake Oswego, Oregon, and serves patients globally through innovative cardiovascular solutions. Biotronik has received FDA 510(k) clearances from total submissions since its first clearance in 1994. The company specializes exclusively in cardiovascular devices, including pacing systems, implantable cardioverter defibrillators, cardiac resynchronization therapies, and electrophysiology cathe...