FDA 510(k) Premarket Notification

K972500 TIR/TIJ AND POLYROX

NOT CLEARED

Mar 4, 1998
244 days to decision

K972500 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k972500/

SUBMISSION DETAILS

Decision	PT
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jul 3, 1997
Decision date	Mar 4, 1998
Days to decision	244 days
Third-party review	No

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...