FDA 510(k) Premarket Notification

CLEARED

K964190 ERA 300 DUAL CHAMBER PACING SYSTEM ANALYZER

Jul 10, 1997
262 days to decision

K964190 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k964190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Oct 21, 1996
Decision date	Jul 10, 1997
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotronik, Inc.**
Location	Lake Oswego, OR, US
Contact	Joseph J Schwoebel
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...