

K042708 ERA 3000 PACING SYSTEM ANALYZEROct 20, 2004
20 days to decisionK042708 · Product code: **DTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k042708/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Sep 30, 2004
Decision date	Oct 20, 2004
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biotronik, Inc.
Location	Lake Oswego, OR, US
Contact	Jon Brumbaugh
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...
