FDA 510(k) Premarket Notification

K022360 ERA 3000

CLEARED

Jan 27, 2003
192 days to decision

K022360 · Product code: **DTA** · Cardiovascular
Source: https://www.510kdatabase.net/k022360/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Pacemaker Electrode Function (DTA)
Date received	Jul 19, 2002
Decision date	Jan 27, 2003
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary
Other names	PA-2 IS-1 ADAPTER; EK-4-N PACEMAKER TEST CABLE; ERA 3000 CHARGER; ERA 3000 BATTERY (TYPE 2); NK-11 POWER SUPP.

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...