

**K922742 HPM 40 HEART PACEMAKER MONITOR**Mar 18, 1993  
283 days to decisionK922742 · Product code: **KRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k922742/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Jun 8, 1992
Decision date	Mar 18, 1993
Days to decision	283 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biotronik, GmbH &amp; Co.</b>
Location	Lake Oswego, OR, US
Contact	STEPHEN K DEOL
510(k) history	18 submissions · 17 cleared · 1989-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922742/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 4, 2026