

**K832959 PACEMAKER SYS. ANALYZER 378**Nov 14, 1983  
76 days to decisionK832959 · Product code: **KRE** · CardiovascularSource: <https://www.510kdatabase.net/k832959/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Aug 30, 1983
Decision date	Nov 14, 1983
Days to decision	76 days
Third-party review	No

**APPLICANT**

---

Company	<b>Siemens Elema AB</b>
Location	Mchenry, IL, US
510(k) history	63 submissions · 60 cleared · 1978-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k832959/> Data sourced from FDA 510(k) public records (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. - Generated May 22, 2026