

**K801022 ULTRA-CHEK PACEMAKER MONITOR**Jun 17, 1980  
48 days to decisionK801022 · Product code: **KRE** · CardiovascularSource: <https://www.510kdatabase.net/k801022/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Apr 30, 1980
Decision date	Jun 17, 1980
Days to decision	48 days
Third-party review	No

**APPLICANT**

---

Company	<b>Powers Medical Systmes</b>
Location	Walker, MI, US
510(k) history	3 submissions · 3 cleared · 1980-1981

---

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

Device record: <https://www.510kdatabase.net/k801022/> 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 2, 2026