

**K913600 WRISTRECORDER CARDIAC EVENT RECORDING SYSTEM**

Oct 16, 1991  
64 days to decision

K913600 · Product code: **DSH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k913600/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Aug 13, 1991
Decision date	Oct 16, 1991
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Ralin Laboratories, Inc.</b>
Location	Beaverton, OR, US
Contact	DONALD M OWEN
510(k) history	1 submissions · 1 cleared · 1991-1991

---

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

Device record: <https://www.510kdatabase.net/k913600/> 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 July 6, 2026