

**K081257 CG-6108 ACT-3L CONTINUOUS ECG MONITOR & ARRHYTHMIA DETECTOR**

May 29, 2008  
27 days to decision

K081257 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k081257/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	May 2, 2008
Decision date	May 29, 2008
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Card Guard Scientific Survival , Ltd.</b>
Location	Israel, IL
Contact	ALEX GONOROVSKY
510(k) history	49 submissions · 49 cleared · 1988-2011

---

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

Device record: <https://www.510kdatabase.net/k081257/> 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 25, 2026