

**K101703 MODIFICATION TO: CG-6108 ACT-3L CONTINUOUS  
ECG MONITOR AND ARRHYTHMIA DETECTOR, MODEL  
FG-00084**Jul 13, 2010  
26 days to decisionK101703 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k101703/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jun 17, 2010
Decision date	Jul 13, 2010
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101703/> 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 May 25, 2026