

**K111745 KING OF HEARTS EXPRESS AF CARDIAC EVENT
RECORDER**Aug 1, 2011
41 days to decisionK111745 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k111745/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Recorder, Magnetic Tape, Medical (DSH) |
| Date received | Jun 21, 2011 |
| Decision date | Aug 1, 2011 |
| Days to decision | 41 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Card Guard Scientific Survival , Ltd. |
| Location | Israel, IL |
| Contact | CLAY ANSELMO |
| 510(k) history | 49 submissions · 49 cleared · 1988-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111745/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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