

**K090936 SINGLE-CHANNEL HANDHELD
ELECTROCARDIOGRAPH, MODEL ECG80A**Aug 25, 2009
145 days to decisionK090936 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k090936/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrocardiograph (DPS) |
| Date received | Apr 2, 2009 |
| Decision date | Aug 25, 2009 |
| Days to decision | 145 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Contec Medical System Co., Ltd. |
| Location | Zhong Shan, Shanghai, CN |
| Contact | Diana Hong |
| 510(k) history | 12 submissions · 12 cleared · 2008-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090936/> 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 June 18, 2026