

**K110463 PCECG-1200 SYSTEM WITH MODULAR ECG
ANALYSIS SYSTEM (MEANS)**Nov 10, 2011
266 days to decisionK110463 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k110463/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Feb 17, 2011 |
| Decision date | Nov 10, 2011 |
| Days to decision | 266 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Norav Medical , Ltd. |
| Location | Plymouth, MN, US |
| Contact | BENRY ARAZY |
| 510(k) history | 4 submissions · 4 cleared · 2000-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110463/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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