

K082812 OMRON MODEL HBP-2070 VITAL SIGNS MONITOROct 22, 2008
28 days to decisionK082812 · Product code: **MWI** · CardiovascularSource: <https://www.510kdatabase.net/k082812/>**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 | Sep 24, 2008 |
| Decision date | Oct 22, 2008 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Omron Healthcare, Inc. |
| Location | Vernon Hills, IL, US |
| Contact | PAUL DRYDEN |
| 510(k) history | 68 submissions · 67 cleared · 1991-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082812/> 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 24, 2026