

K040194 COMPUMEDICS SUMMIT IPApr 23, 2004
86 days to decisionK040194 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k040194/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilatory Effort Recorder (MNR) |
| Date received | Jan 28, 2004 |
| Decision date | Apr 23, 2004 |
| Days to decision | 86 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Compumedics USA, Ltd. |
| Location | El Paso, TX, US |
| Contact | ELVIRA GARCIA |
| 510(k) history | 3 submissions · 3 cleared · 2003-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040194/> 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 May 25, 2026