

K040862 GUARDIAN NEONATE CPAP/HUMIDIFICATION SYSTEMJun 30, 2004
89 days to decisionK040862 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k040862/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received | Apr 2, 2004 |
| Decision date | Jun 30, 2004 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Caradyne, Ltd. |
| Location | Mccordsville, IN, US |
| Contact | JOHN O'NEAL;DEA |
| 510(k) history | 5 submissions · 5 cleared · 1999-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040862/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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