

K944400 PEDI-CAPSep 27, 1994
19 days to decisionK944400 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k944400/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK) |
| Date received | Sep 8, 1994 |
| Decision date | Sep 27, 1994 |
| Days to decision | 19 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nellcor, Inc. |
| Location | Mchenry, IL, US |
| Contact | MARSHA J STONE |
| 510(k) history | 18 submissions · 18 cleared · 1982-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944400/> 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 26, 2026