

K083688 PULMONETIC SYSTEMS LTV 1200 MR CONDITIONAL VENTILATORMar 18, 2009
96 days to decisionK083688 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k083688/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Continuous, Facility Use (CBK) |
| Date received | Dec 12, 2008 |
| Decision date | Mar 18, 2009 |
| Days to decision | 96 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Pulmonetic Systems, Inc. |
| Location | Colton, CA, US |
| Contact | ROBERT C SAMEC |
| 510(k) history | 12 submissions · 11 cleared · 1998-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083688/> 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 24, 2026