

K051869 NEOBLUE COZY LED PHOTOTHERAPY SYSTEMOct 7, 2005
88 days to decisionK051869 · Product code: **LBI** · General HospitalSource: <https://www.510kdatabase.net/k051869/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Neonatal Phototherapy (LBI) |
| Date received | Jul 11, 2005 |
| Decision date | Oct 7, 2005 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Natus Medical, Inc. |
| Location | San Carlos, CA, US |
| Contact | LUANNE NG |
| 510(k) history | 12 submissions · 12 cleared · 1995-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k051869/> 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 20, 2026