

**K111547 BILI-THERAPY PAD TYPE**Apr 12, 2012  
314 days to decisionK111547 · Product code: **LBI** · General Hospital  
Source: <https://www.510kdatabase.net/k111547/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Unit, Neonatal Phototherapy (LBI)  |
| Date received         | Jun 3, 2011                        |
| Decision date         | Apr 12, 2012                       |
| Days to decision      | 314 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Atom Medical Corporation</b>         |
| Location       | Bunkyo-Ku, Tokyo, JP                    |
| Contact        | PAUL DRYDEN                             |
| 510(k) history | 10 submissions · 10 cleared · 2010-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111547/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026