

**K011355 BIOLIGHT PCD**Jan 17, 2002  
259 days to decisionK011355 · Product code: **ILY** · Physical MedicineSource: <https://www.510kdatabase.net/k011355/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Lamp, Infrared, Therapeutic Heating (ILY) |
| Date received         | May 3, 2001                               |
| Decision date         | Jan 17, 2002                              |
| Days to decision      | 259 days                                  |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Biolight International AB</b>      |
| Location       | Minneapolis,, MN, US                  |
| Contact        | CONSTANCE G BUNDY                     |
| 510(k) history | 1 submissions · 1 cleared · 2002-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011355/> 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 June 29, 2026