

**K142332 BT-400**Mar 20, 2015  
212 days to decisionK142332 · Product code: **LBI** · General HospitalSource: <https://www.510kdatabase.net/k142332/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Aug 20, 2014
Decision date	Mar 20, 2015
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bio-Med USA</b>
Location	Ramsey, NJ, US
Contact	Young Chi
510(k) history	1 submissions · 1 cleared · 2015-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142332/> 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 4, 2026