

**K243372 BiliWrap**May 29, 2025  
211 days to decisionK243372 · Product code: **LBI** · General Hospital  
Source: <https://www.510kdatabase.net/k243372/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Oct 30, 2024
Decision date	May 29, 2025
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gerium Medical, Ltd.</b>
Location	Yavne, IL
Contact	Noam Rubin Tal
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedoss, Inc.</b>
Contact	Bosmat Friedman-Cox

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243372/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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