FDA 510(k) Premarket Notification

# K243372 BiliWrap

**CLEARED**

May 29, 2025
211 days to decision

K243372 · 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

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

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **ProMedoss, Inc.** |
| Contact | Bosmat Friedman-Cox |

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