

K172656 BiliLuxMay 1, 2018
238 days to decisionK172656 · Product code: **LBI** · General HospitalSource: <https://www.510kdatabase.net/k172656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Sep 5, 2017
Decision date	May 1, 2018
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Draeger Medical Systems, Inc.
Location	Danvers, MA, US
Contact	Gale Winarsky
510(k) history	48 submissions · 48 cleared · 2003-2025

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