

K053568 BILISOFT PHOTOTHERAPY SYSTEMApr 17, 2006
116 days to decisionK053568 · Product code: **LBI** · General Hospital
Source: <https://www.510kdatabase.net/k053568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Dec 22, 2005
Decision date	Apr 17, 2006
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lumitex, Inc.
Location	Cleveland, OH, US
Contact	JEFF WILLIAMS
510(k) history	3 submissions · 3 cleared · 1991-2012

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