

K160305 neoBLUE® LED Phototherapy SystemMay 27, 2016
113 days to decisionK160305 · Product code: **LBI** · General Hospital
Source: <https://www.510kdatabase.net/k160305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Feb 4, 2016
Decision date	May 27, 2016
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Natus Medical Incorporated
Location	Oakville, Ontario, CA
Contact	Judy Buckham
Website	http://www.natus.com/
510(k) history	10 submissions · 10 cleared · 2010-2018

Natus Medical Incorporated develops diagnostic and monitoring devices for neurological, sensory, and newborn care applications. The company operates with a manufacturing facility in Oakville, Ontario, Canada, and serves healthcare providers globally through neurodiagnostic and sensory screening solutions. Natus Medical received FDA 510(k) clearances from total submissions between 2010 and 2018. The company's cleared devices span General Hospital, Neurology, Ear/Nose/Throat, and Ophthalmic categories, including phototherapy systems, hearing screeners, neurophysiology monit...
