

K182178 neoBLUE blanket LED Phototherapy SystemDec 13, 2018
122 days to decisionK182178 · Product code: **LBI** · General Hospital
Source: <https://www.510kdatabase.net/k182178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Aug 13, 2018
Decision date	Dec 13, 2018
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	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...