

K200031 Neonatal Phototherapy SystemOct 5, 2020
272 days to decisionK200031 · Product code: **LBI** · General HospitalSource: <https://www.510kdatabase.net/k200031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Jan 7, 2020
Decision date	Oct 5, 2020
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avalon Biomedical (Shenzhen) Limited
Location	Longhua District, CN
Contact	Eva Zhu
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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