FDA 510(k) Premarket Notification

CLEARED

K210289 Infant Phototherapy Equipment

May 28, 2021
115 days to decision

K210289 · Product code: **LBI** · General Hospital
Source: https://www.510kdatabase.net/k210289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Feb 2, 2021
Decision date	May 28, 2021
Days to decision	115 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bistos Co., Ltd.**
Location	Flintville, TN, US
Contact	Dae Eun Kim
510(k) history	11 submissions · 11 cleared · 2005-2025

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov