

**K002414 PHOTOTHERAPY LAMP 900IW501JE
PHOTOTHERAPY POWER MODULE 900IW502JE**Sep 25, 2000
49 days to decisionK002414 · Product code: **LBI** · General Hospital
Source: <https://www.510kdatabase.net/k002414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Aug 7, 2000
Decision date	Sep 25, 2000
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fisher &Paykel Healthcare , Ltd.
Location	Auckland, New Zealand, NZ
Contact	BRETT WHISTON
Website	https://www.fphcare.com/
510(k) history	70 submissions · 70 cleared · 1988-2025

Fisher &Paykel Healthcare, Ltd. is a medical device manufacturer based in Auckland, New Zealand. The company has driven innovation in healthcare technologies for over 50 years. Fisher &Paykel Healthcare has received FDA 510(k) clearances from total submissions since 1988. The company specializes in Anesthesiology devices, which represent 91% of its regulatory submissions. The latest clearance was granted in 2025, confirming active ongoing development. Recent cleared devices include high-flow nasal therapy systems, noninvasive ventilation masks, and respiratory support int...

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