

K103527 AVIATOR TRANSPORT INCUBATOR WITH MASIMO PULSEOX, AVIATOR TRANSPORT INCUBATOR WITH NELLCOR PULSEOXApr 15, 2011
135 days to decisionK103527 · Product code: FPL · General Hospital
Source: <https://www.510kdatabase.net/k103527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Incubator, Neonatal Transport (FPL)
Date received	Dec 1, 2010
Decision date	Apr 15, 2011
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	International Biomedical, Ltd.
Location	Austin, TX, US
Contact	AMY PIEPER
510(k) history	6 submissions · 6 cleared · 2008-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103527/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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