

K182956 Puffin Lite Infant Resuscitation SystemJan 18, 2019
86 days to decisionK182956 · Product code: **BTL** · Anesthesiology
Source: <https://www.510kdatabase.net/k182956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Oct 24, 2018
Decision date	Jan 18, 2019
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	International Biomedical
Location	Austin, TX, US
Contact	Amy Pieper
510(k) history	8 submissions · 8 cleared · 2014-2022

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