

K121747 FACEFIT AND FACEFIT PORTED NON-INVASIVE VENTILATION MASKSMar 14, 2013
273 days to decisionK121747 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k121747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jun 14, 2012
Decision date	Mar 14, 2013
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intersurgical Incorporated
Location	Liverpool, NY, US
Contact	MICHAEL ZALEWSKI
510(k) history	3 submissions · 3 cleared · 2013-2015

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