

K181583 Adult Single Use Resuscitator Bag without Pressure Relief, Adult Single Use Resuscitator Bag + Pressure Relief 40CMH20, Adult Single Use Resuscitator Bag + Pressure Relief 60CMH20, Pediatric Single Use Resuscitator Bag + Pressure Relief 40CMH20, Infant Single Use Resuscitator Bag + Pressure Relief 40CMH20

Dec 7, 2018
175 days to decision

K181583 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k181583/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jun 15, 2018
Decision date	Dec 7, 2018
Days to decision	175 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Flexicare Medical Limited.
Location	Mountain Ash, GB
Contact	Joel Biddle
510(k) history	8 submissions · 8 cleared · 2016-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181583/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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