

K150685 Skynector CPAP MaskAug 24, 2015
160 days to decisionK150685 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k150685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 17, 2015
Decision date	Aug 24, 2015
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sky Wise Medical Instrument (Shen Zhen) Co., Ltd.
Location	Shenzhen, Guang Dong, CN
Contact	Field Fu
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150685/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026