

K253044 RXiBreeze PAP System (RXiBreeze 20C)

Jul 23, 2026
304 days to decision

K253044 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k253044/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 22, 2025
Decision date	Jul 23, 2026
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Resvent Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Harry Wang
510(k) history	1 submissions · 1 cleared · 2026-2026