

K041823 PIONEER U121 SERIES CPAPMay 10, 2005
308 days to decisionK041823 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k041823/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jul 6, 2004
Decision date	May 10, 2005
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merits Health Products Co., Ltd.
Location	Cape Coral, FL, US
Contact	STEVE CHAO
510(k) history	19 submissions · 19 cleared · 1996-2022

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