

K130322 SPM-300Nov 15, 2013
280 days to decisionK130322 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k130322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Feb 8, 2013
Decision date	Nov 15, 2013
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionet Co., Ltd.
Location	Wonju, Kwangwon-Do, KR
Contact	MARC GOODMAN
510(k) history	11 submissions · 11 cleared · 2005-2023

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