

K241843 TD-7301 Spirometer (TD-7301)Nov 20, 2024
147 days to decisionK241843 · Product code: **BZG** · AnesthesiologySource: <https://www.510kdatabase.net/k241843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jun 26, 2024
Decision date	Nov 20, 2024
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gostar Co., Ltd.
Location	New Taipei City, TW
Contact	Pei-Fen Yang
510(k) history	3 submissions · 3 cleared · 2023-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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