

**K233855 AIIPEP**Feb 2, 2024  
59 days to decisionK233855 · Product code: **BWF** · AnesthesiologySource: <https://www.510kdatabase.net/k233855/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Dec 5, 2023
Decision date	Feb 2, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Enchant Tek Co. , Ltd.</b>
Location	Yilan County, TW
Contact	Leonard Ling
510(k) history	2 submissions · 2 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233855/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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