FDA 510(k) Premarket Notification

K251777 MESI mTABLET SPIRO

CLEARED

Mar 2, 2026
265 days to decision

K251777 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k251777/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jun 10, 2025
Decision date	Mar 2, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mesi D.O.O.**
Location	Ljubljana, SI
Contact	Nejc Ludvik
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Paladin Medical, Inc.**
Contact	Elaine Duncan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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Device record: https://www.510kdatabase.net/k251777/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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