

K250464 Enlight 2100 (TPL-E2103-0)Sep 10, 2025
204 days to decisionK250464 · Product code: **QEB** · Anesthesiology
Source: <https://www.510kdatabase.net/k250464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Electrical Impedance Tomograph (QEB)
Date received	Feb 18, 2025
Decision date	Sep 10, 2025
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Timpel S.A.
Location	Sao Paulo, BR
Contact	Rafael Holzacker
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250464/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026