FDA 510(k) Premarket Notification

K250464 Enlight 2100 (TPL-E2103-0)

CLEARED

Sep 10, 2025
204 days to decision

K250464 · 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 Holzhacker
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