

K211135 Enlight 2100Jan 6, 2022
265 days to decisionK211135 · Product code: **QEB** · Anesthesiology
Source: <https://www.510kdatabase.net/k211135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Electrical Impedance Tomograph (QEB)
Date received	Apr 16, 2021
Decision date	Jan 6, 2022
Days to decision	265 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)

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