FDA 510(k) Premarket Notification

K211135 Enlight 2100

CLEARED

Jan 6, 2022
265 days to decision

K211135 · 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 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