FDA 510(k) Premarket Notification

# K222897 Enlight 2100

**CLEARED**

Mar 7, 2023
165 days to decision

K222897 · Product code: **QEB** · Anesthesiology
Source: https://www.510kdatabase.net/k222897/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilatory Electrical Impedance Tomograph (QEB) |
| Date received | Sep 23, 2022 |
| Decision date | Mar 7, 2023 |
| Days to decision | 165 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 Holtzhacker |
| 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