FDA 510(k) Premarket Notification

K243765 LuMon(TM) System

CLEARED

Aug 7, 2025
244 days to decision

K243765 · Product code: **QEB** · Anesthesiology
Source: https://www.510kdatabase.net/k243765/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Electrical Impedance Tomograph (QEB)
Date received	Dec 6, 2024
Decision date	Aug 7, 2025
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sentec AG**
Location	Egale, WI, US
Contact	Caroline Moller
510(k) history	5 submissions · 5 cleared · 2007-2025

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