

**K243765 LuMon(TM) System**Aug 7, 2025  
244 days to decisionK243765 · Product code: **QEB** · Anesthesiology  
Source: <https://www.510kdatabase.net/k243765/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedic Consulting, LLC</b>
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243765/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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