

K261389 PRO2 Elite Plus Oxygen Analyzer (PRO2PLUS-1)

Jul 30, 2026  
93 days to decision

K261389 · Product code: CCL · Anesthesiology  
Source: <https://www.510kdatabase.net/k261389/>

SUBMISSION DETAILS

|                       |                                            |
|-----------------------|--------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Analyzer, Gas, Oxygen, Gaseous-phase (CCL) |
| Date received         | Apr 28, 2026                               |
| Decision date         | Jul 30, 2026                               |
| Days to decision      | 93 days                                    |
| Third-party review    | No                                         |
| Combination product   | No                                         |
| PCCP authorized       | No                                         |
| Summary / Statement   | Summary                                    |

APPLICANT

|                |                                         |
|----------------|-----------------------------------------|
| Company        | <b>Salter Labs</b>                      |
| Location       | Mchenry, IL, US                         |
| Contact        | Robert Yamashita                        |
| 510(k) history | 49 submissions · 49 cleared · 1978-2026 |

REGULATORY CONSULTANT

|                 |                           |
|-----------------|---------------------------|
| Consulting firm | <b>Airlife Finland OY</b> |
| Contact         | Tanja-Maria Ranta         |

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