

**K190561 NICU V&apos;02**Sep 4, 2020  
549 days to decisionK190561 · Product code: **BZL** · Anesthesiology  
Source: <https://www.510kdatabase.net/k190561/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Computer, Oxygen-uptake (BZL)      |
| Date received         | Mar 5, 2019                        |
| Decision date         | Sep 4, 2020                        |
| Days to decision      | 549 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Cosmed Nordic Aps</b>              |
| Location       | Odense, DK                            |
| Contact        | Peter Clemensen                       |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

**REGULATORY CONSULTANT**

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|-----------------|---------------------------|
| Consulting firm | <b>Wood Burditt Group</b> |
| Contact         | H. Carl Jenkins           |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190561/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 21, 2026