

**K231064 ReddyPort Elbow**Jul 13, 2023  
90 days to decisionK231064 · Product code: **MNS** · Anesthesiology  
Source: <https://www.510kdatabase.net/k231064/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Ventilator, Continuous, Non-life-supporting (MNS) |
| Date received         | Apr 14, 2023                                      |
| Decision date         | Jul 13, 2023                                      |
| Days to decision      | 90 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Smd Manufacturing, LLC</b>         |
| Location       | Salt Lake City, UT, US                |
| Contact        | Jared Spendlove                       |
| 510(k) history | 2 submissions · 2 cleared · 2018-2023 |

**REGULATORY CONSULTANT**

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|-----------------|----------------------|
| Consulting firm | <b>leanRAQA, LLC</b> |
| Contact         | Tianna Benson        |

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231064/> 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 May 27, 2026