

**K203400 Corrugated tube with mouthpiece accessory**Jun 14, 2021  
207 days to decisionK203400 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k203400/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Nebulizer (direct Patient Interface) (CAF) |
| Date received         | Nov 19, 2020                               |
| Decision date         | Jun 14, 2021                               |
| Days to decision      | 207 days                                   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                    |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Trudell Medical International</b>  |
| Location       | London, CA                            |
| Contact        | Marianne Tanton                       |
| 510(k) history | 9 submissions · 9 cleared · 2015-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203400/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026