

**K000653 AERONOX UNIVERSAL, MODEL P/N 360000,  
AERONOX BEDSIDE, MODEL P/N 360001, AERONOX  
TRANSPORT TRANSPORT, MODEL P/N 360002**

Aug 4, 2000  
158 days to decision

K000653 · Product code: **MRN** · Anesthesiology  
Source: <https://www.510kdatabase.net/k000653/>

**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Apparatus, Nitric Oxide Delivery (MRN) |
| Date received         | Feb 28, 2000                           |
| Decision date         | Aug 4, 2000                            |
| Days to decision      | 158 days                               |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Pulmonox Medical Corp.</b>         |
| Location       | Tofield, Alberta, CA                  |
| Contact        | PAULA TOMAT                           |
| 510(k) history | 1 submissions · 1 cleared · 2000-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k000653/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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