

**K001318 CPAP SYSTEM, MODEL 102001**Jul 20, 2000  
85 days to decisionK001318 · Product code: **BYE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k001318/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Attachment, Breathing, Positive End Expiratory Pressure (BYE) |
| Date received         | Apr 26, 2000  |
| Decision date         | Jul 20, 2000  |
| Days to decision      | 85 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sims Portex, Inc.</b>                |
| Location       | Keene, NH, US                           |
| Contact        | BRIAN D FARIAS                          |
| 510(k) history | 12 submissions · 12 cleared · 1998-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001318/> 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 25, 2026