

**K182394 WiZARD 310/320 Series CPAP Mask**May 17, 2019  
255 days to decisionK182394 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k182394/>**SUBMISSION DETAILS**

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|                       |                                               |
|-----------------------|-----------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received         | Sep 4, 2018                                   |
| Decision date         | May 17, 2019                                  |
| Days to decision      | 255 days                                      |
| Third-party review    | No                                            |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Apex Medical Corp.</b>               |
| Location       | Shi-Chih, Taipei Hsien, TW              |
| Contact        | Frank Lin                               |
| 510(k) history | 30 submissions · 30 cleared · 1997-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182394/> 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 14, 2026