

**K251086 PnueAira (PNCU-01)**Aug 18, 2025  
131 days to decisionK251086 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k251086/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Sleeve, Limb, Compressible (JOW)   |
| Date received         | Apr 9, 2025                        |
| Decision date         | Aug 18, 2025                       |
| Days to decision      | 131 days                           |
| Third-party review    | Yes                                |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Biotab, LLC</b>                    |
| Location       | St. Louis, MO, US                     |
| Contact        | Evan Hall                             |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Regulatory Technology Services, LLC</b> |
| Contact         | Prithul Bom                                |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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