

**K251101 AIRO Suction Unit (AIRO-01)**Apr 26, 2025  
15 days to decisionK251101 · Product code: **BTA** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k251101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Apr 11, 2025
Decision date	Apr 26, 2025
Days to decision	15 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cro, LLC</b>
Location	Missoula, MT, US
Contact	Jeffrey Boardman
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251101/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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