

**K213969 VisionAir Patient-Specific Airway Stent**Oct 7, 2022  
291 days to decisionK213969 · Product code: **NWA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k213969/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Tracheal, Preformed/molded (NWA)
Date received	Dec 20, 2021
Decision date	Oct 7, 2022
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>New Cos Inc. DbA Visionair Solutions</b>
Location	Cleveland, OH, US
Contact	Keith Grafmeyer
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213969/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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