

**K253569 Atmo Gas Capsule System**May 22, 2026  
186 days to decisionK253569 · Product code: **NYV** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k253569/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Motility System, Capsule (NYV)
Date received	Nov 17, 2025
Decision date	May 22, 2026
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Atmo Biosciences, Ltd.</b>
Location	Box Hill, AU
Contact	Ian Macfarlane
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253569/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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