

K250940 Atmo Gas Capsule SystemJun 26, 2025
90 days to decisionK250940 · Product code: **NYV** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Motility System, Capsule (NYV)
Date received	Mar 28, 2025
Decision date	Jun 26, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Atmo Biosciences, Ltd.
Location	Box Hill, AU
Contact	Ian Macfarlane
510(k) history	1 submissions · 1 cleared · 2025-2025

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