

K261369 GI Genius™ Module 300 (GGM300-US)May 30, 2026
33 days to decisionK261369 · Product code: **QNP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k261369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Apr 27, 2026
Decision date	May 30, 2026
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ColonPRO™ US (CPRO403S-US)

APPLICANT

Company	Cosmo Artificial Intelligence - Ai, Ltd.
Location	Dublin, IE
Contact	Nhan Ngo Dinh
510(k) history	6 submissions · 5 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Donawa Lifescience Consulting Srl
Contact	Roger Gray

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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