

K241887 GI Genius™ Module 100 (GGM100.US)Jul 25, 2024
27 days to decisionK241887 · Product code: **QNP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Jun 28, 2024
Decision date	Jul 25, 2024
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GI Genius™ Module 200 (GGM200.US); ColonPRO™ 4.0 (CPRO40.US); GI Genius™ Module 300 (GGM300-US); ColonPRO™ 4.0 (CPRO40S-US)

APPLICANT

Company	Cosmo Artificial Intelligence - Ai, Ltd.
Location	Dublin, IE
Contact	Ngo Dinh Nhan
510(k) history	5 submissions · 4 cleared · 2021-2024

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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