

**K231143 GI Genius System 100 and GI Genius System 200**May 19, 2023  
28 days to decisionK231143 · Product code: **QNP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k231143/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Apr 21, 2023
Decision date	May 19, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Donawa Lifescience Consulting Srl</b>
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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