

K211951 GI GeniusJul 23, 2021
30 days to decisionK211951 · Product code: **QNP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Jun 23, 2021
Decision date	Jul 23, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cosmo Artificial Intelligence - Ai, Ltd.
Location	Dublin, IE
Contact	Nhan Ngo Dinh
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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