FDA 510(k) Premarket Notification

CLEARED

K233964 GI Genius™ Module 100 (GGM100.US)

Jan 12, 2024
28 days to decision

K233964 · Product code: **QNP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233964/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointesinal Lesion Software Detection System (QNP)
Date received	Dec 15, 2023
Decision date	Jan 12, 2024
Days to decision	28 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)

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