May 29, 2026

Cosmo Artificial Intelligence - Ai, Ltd.
℅ Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
Rome, 00153
Italy

Re: K261369
Trade/Device Name: GI Genius™ Module 300 (GGM300-US);ColonPRO™ US (CPRO403S-US)
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: April 26, 2026
Received: April 27, 2026

Dear Roger Gray:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SIVAKAMI VENKATACHALAM -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261369

Please provide the device trade name(s).

GI Genius™ Module 300 (GGM300-US);
ColonPRO™ US (CPRO403S-US)

Please provide your Indications for Use below.

The GI Genius™ system is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white-light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. The GI Genius™ computer-assisted detection device is limited for use with standard white-light endoscopy imaging only. This device is not intended to replace clinical decision making.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

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510(k) Summary

510(k) Reference:	K261369
Device Name:	GI Genius™ Module 300 (GGM300-US); ColonPRO™ US (CPRO403S-US).
Type of 510(k) submission:	Special
Date of submission:	24 April 2026
510(k) Owner and Submitter:	Cosmo Artificial Intelligence - AI Ltd Riverside II, Sir John Rogerson's Quay Dublin D02 KV60 Ireland
FDA Establishment Reg. Number:	3018899987
Specification Developer:	Linkverse Srl via Ostiense 131/L 00154 Rome, Italy
Owner/Operator Reg. Number:	3018901422
510(k) Application Correspondent:	Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome, Italy
Phone:	+39 06 578 2665
Email:	rgray@donawa.com
FDA Product Code:	QNP
FDA Regulation Number:	21 CFR 876.1520
FDA Classification Name:	Gastrointestinal lesion software detection system
Classification Panel:	Gastroenterology and Urology
FDA Classification:	Class II

Indications for Use:
The GI Genius™ system is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white-light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. The GI Genius™ computer-assisted detection device is limited for use with standard white-light endoscopy imaging only. This device is not intended to replace clinical decision making.

The indications for use statement is the same as that of the original unmodified (predicate) device, as cleared under K241887.

Device Description:
GI Genius™ is an artificial intelligence-based device that has been trained to process colonoscopy images containing regions consistent with colorectal lesions like polyps, including those with flat (non-polypoid) morphology.

The GI Genius™ system is composed of software (namely, ColonPRO™ US) and hardware (namely, GI Genius™ Module 300).

GI Genius™ Module 300 is compatible with Video Processors featuring SDI (SMPTE 259M), HD-SDI (SMPTE 292M), 3G/SDI (SMPTE 424 M) output ports and endoscopic display monitors featuring SDI (SMPTE 259M), HD-SDI (SMPTE 292M), 3G/SDI (SMPTE 424 M) input ports. GI Genius™ Module 300 is also compatible with Video Processors featuring the 4K UHD standard (12G-SDI SMPTE ST 2082).

The GI Genius™ system is connected between the video processor and the endoscopic display monitor. When first switched on, the endoscopic field of view is clearly identified by four corner markers, and a blinking green square indicator appears on the connected endoscopic display monitor to state that the system is ready to function.

During live video streaming of the endoscopic video image, GI Genius™ system generates a video output on the endoscopic display monitor that contains the original live video together with superimposed green square markers that will appear when a polyp or other lesion of interest is detected, accompanied by a short sound. These markers will not be visible when no lesion detection occurs.

The operating principle of the subject device is identical to that of the predicate device, this being a computer-assisted detection device used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device includes hardware to support interfacing with video endoscopy systems.

The baseline clinical validation for the subject device was conducted and reviewed in DEN200055 and is still applicable to the version of the device that is the subject of this submission.

Design changes:
This Special 510(k) submission describes the design changes incorporated into GI Genius™ system following FDA clearance under K241887. The device software version number as cleared under K241887 was 4.0.0-S and Operating System version was 1.0.0; the device software version that is subject to this Special 510(k) is 4.0.3-S and Operating System version is 1.0.3.

Two design changes are detailed in this submission that fall within the FDA guideline for submittal of a new 510(k). The first is to allow the use of background non-medical software in separate ‘software containers’ at the same time as the medical lesion detection software ColonPRO™ US in its separate container. The second is to allow the existing connectivity features of the device to be used for user-interaction with the background software containers via external communication devices. Both design changes introduce ‘other functions’ in the meaning of the FDA guideline on multiple function device products, given that they are unrelated to the medical application of the subject device, which is the same as in the predicate device.

The proposed first change is based on the device’s internal software features that allow more than one software container to run at the same time. In the unmodified version of the device there is only one software

container being executed, that is ColonPRO™ US. Nonetheless, the device is also capable of managing the concurrent execution of more software containers as an additional non-medical function, thus qualifying the proposed subject device as a multiple function device product with a multicontainer management functionality that is available to users.

The multicontainer management functionality is intended to allow the user to operate non-medical device software, in real time, that can support daily manual operations commonly executed by the user, such as clinical management, reporting, and health IT functions, thus easing user workload. The multicontainer management functionality allows only the medical software container to be executed in foreground and thus the subject device still provides the same onscreen overlay as the predicate device, while any other software container can be executed in background only, with no output on the main endoscopy display, which has no means of interaction with any background software containers through the subject device user interface. Availability of any software container remains under the exclusive control of the manufacturer.

The proposed second change is to allow use of the current device connectivity features, both local and remote, to allow the user to interact with the background software containers on external devices and exchange and transfer data in real time. The unmodified device already features connectivity functionalities, but they have previously been used only by the manufacturer for service activities. In the proposed subject device, connections will be made available to users and to authorized third parties for exchange of information and data, under conditions and limitations defined exclusively by the manufacturer.
The two changes will result in an update of the labelling of the predicate device to inform the user of the multicontainer management functionality and of its connectivity features, as newly available functions of the device.

These design changes do not affect the intended use of the GI Genius™ system, nor do they modify the algorithmic function, performance, or clinical output of the medical software container ColonPRO™ US. The fundamental scientific technology remains unchanged compared to the predicate device cleared under K241887.

Non-clinical testing:
The following non-clinical verification/validation activities have been completed:

- Risk mitigation measures identified during Risk Management have been successfully verified or validated, as applicable, with specific reference to:
  - Verification and validation that resources management controls ensure that execution of background software containers does not impact the performance, timing, image processing, or output generation of the medical software container ColonPRO™ US. The foreground medical software container is always executed with prioritized system resources and with exclusive control of the foreground execution environment.
  - Verification and validation that a failure or malfunction of a background software container or associated connectivity feature cannot directly or indirectly alter the medical function and output provided by ColonPRO™ US.
  - Verification and validation that built-in design features prevent presence of critical tasks that can lead the user to use errors when the device is used for its established medical purpose.
  - Verification that labeling updates inform the users of the availability, purpose, and limitations of the multicontainer management functionality and associated connectivity features. Clear distinction between the medical and non-medical functions and statement that background software containers do not provide medical information, clinical decision support, or user interaction through the GI Genius™ system interface.

- Cybersecurity of activated communication and data transmission has been included and risk mitigation measures introduced and successfully verified or validated, as applicable, with specific reference to:
  - Verification and validation that external connections do not permit control of, modification to, or interaction with the foreground medical software container.
  - Verification and validation that the potential attack surface is addressed through software architecture controls, access limitations, and security monitoring measures.
  - Verification and validation that container isolation failure, resource contention, and container coexistence is addressed through software architecture controls, access limitations, and security monitoring measures.
- Verification of the software at the system level. Each element of the SRS was tested and found to meet specified requirements, testing 37 Units and 25 Items, encompassing 206 software requirements.
- Validation of the software at the user level has been carried out, incorporating tests sufficient for the validation of the SRS.

The results of the above testing aid demonstration of substantial equivalence of the subject device with the predicate device, as the same methodology and test protocols have been used where applicable.

Substantial equivalence:
The predicate device for the subject device is the pre-modification version of the same device, GI Genius™ Module 300 with software ColonPRO™ 4.0, FDA-cleared under K241887 on 25 July 2024:

Predicate Device:	GI Genius™ Module 300 with ColonPRO™ 4.0
Sponsor:	Cosmo Artificial Intelligence - AI Ltd
510(k) Number:	K241887
Clearance Date:	25 July 2024
FDA Product Code:	QNP
Classification Name:	Gastrointestinal lesion software detection system
Regulation No:	21 CFR 876.1520
Class:	II

Predicate device comparison table:
The two proposed changes relate to the update of labeling to inform the user of the available other functions given by the multicontainer management functionality and associated connectivity features, whereas any other technical feature, use, and medical claim between the subject and predicate device remain the same.

Table 1 provides evidence of substantial equivalence of the subject device with the predicate device.

Table 1: Predicate device comparison table

Characteristic	Subject device	Predicate device	Comparison
Device name	GI Genius™ Module 300 (GGM300-US, operating system v.1.0.3) ColonPRO™ US (CPRO403S-US)	GI Genius™ Module 300 (GGM300-US, operating system v.1.0.0) ColonPRO™ 4.0 (CPRO40S-US)	Minor software updates to internal software functionalities
Manufacturer	Linkverse S.r.l., Italy	Linkverse S.r.l., Italy	Same
FDA clearance	This submission	K241887	N/A
FDA Reg name	Gastrointestinal lesion software detection system	Gastrointestinal lesion software detection system	Same
FDA Reg #	21 CFR 876.1520	21 CFR 876.1520	Same

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Table 1: Predicate device comparison table			
Characteristic	**Subject device**	**Predicate device**	**Comparison**
FDA Product Code	QNP	QNP	Same
Indications for Use	The GI Genius™ system is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white-light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. The GI Genius™ computer-assisted detection device is limited for use with standard white-light endoscopy imaging only. This device is not intended to replace clinical decision making.	The GI Genius System is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white-light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. The GI Genius computer-assisted detection device is limited for use with standard white-light endoscopy imaging only. This device is not intended to replace clinical decision making.	Same
Video delay, signal in to signal out	29 µs (< 5.75 ms limit)	29 µs (< 5.75 ms limit)	Same
Lesion-based sensitivity	88.07%	88.07%	Same
Frame level performance (150 videos / 338 polyps)	True positive: 277,738 True negative: 5,248,406 False positive: 95,391 False negative: 184,052	True positive: 277,738 True negative: 5,248,406 False positive: 95,391 False negative: 184,052	Same
True positive rate per frame	Mean: 60.14 % % of polyps: 100 %	Mean: 60.14 % % of polyps: 100 %	Same
False positive rate per frame	Mean: 1.79%	Mean: 1.79%	Same
Frame-Based TPr/FPr ROC curve, AOC	0.826	0.826	Same
False positive clusters per patient	< 500 ms: 97 > 500 ms: 10	< 500 ms: 97 > 500 ms: 10	Same
Additional video processor	none	N/A	Same
Software other function	Procedure Highlights function Multicontainer management	Procedure Highlights function	Background software containers available to users through an internal non-medical function of the device
Electrical safety	IEC/EN 60601-1	IEC/EN 60601-1	Same
Electromagnetic compatibility	IEC/EN 60601-1-2	IEC/EN 60601-1-2	Same
LAN port USB port QSFP port	Yes, functional to user	Yes, non-functional to user	Connectivity available to users as non-medical function

Conclusion

The subject and predicate devices have identical indications for use and fundamental technological characteristics. The subject device and predicate device share the same medical performance as no change has been made to the software functions related to detection of suspected lesions. Verification and validation tests performed on risk mitigation measures for both safety of use and cybersecurity demonstrate that the

subject device is substantially equivalent to the predicate device, which is already in interstate commerce within the USA. Therefore, the subject device is as safe and effective as the predicate device.