July 25, 2024

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

Re: K241887
Trade/Device Name: GI Genius™ Module 100 (GGM100.US); GI Genius™ Module 200 (GGM200.US); ColonPRO™ 4.0 (CPRO40.US); GI Genius™ Module 300 (GGM300-US); ColonPRO™ 4.0 (CPRO40S-US)
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: June 28, 2024
Received: June 28, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241887

Device Name

GI Genius™ Module 100 (GGM100.US);
GI Genius™ Module 200 (GGM200.US);
ColonPRO™ 4.0 (CPRO40.US);
GI Genius™ Module 300 (GGM300-US);
ColonPRO™ 4.0 (CPRO40S-US)

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

COSMO Pharmaceuticals

ATTACHMENT 04

510(k) Summary

510(k) Reference:	K241887
Device Name:	GI Genius™ Module 100 (GGM100.US); GI Genius™ Module 200 (GGM200.US); ColonPRO™ 4.0 (CPRO40.US); GI Genius™ Module 300 (GGM300-US); ColonPRO™ 4.0 (CPRO40S-US).
Type of 510(k) submission:	Special
Date of submission:	27 June 2024
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 K233964.

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.

GI Genius is composed of software (namely, ColonPRO™ 4.0) and hardware (namely, GI Genius™ Module 100, 200, and 300).

GI Genius™ Module 100, 200, and 300 are 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 200 and 300 are 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 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 and the accessories given by the footswitch and the USB K-switch.

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 following FDA clearance under K233964. The device software version number as cleared under K233964 was 4.0.0; the device software version that is the subject of this Special 510(k) is still 4.0.0 for GI Genius™ Module 100 and GI Genius™ Module 200, whereas it is 4.0.0-S for GI Genius™ Module 300 and it differs only in the re-build of the same software to create a software container compatible with the changed hardware unit.

Three types of design change are detailed in this submission that fall within the FDA guideline for submittal of a new 510(k). The first two changes are consequence of the improvement to the device core elements of providing technical capability of accelerating software featuring generative AI inference models, designed for medical applications, for low-latency, and real-time applications given by the NVIDIA IGX Orin™ kit.

The technical specifications are identical between the predicate and the subject device except for the following hardware change:

1. The NVIDIA IGX Orin™ kit replaces the current motherboard, GPU, CPU, and RAM;
2. The Deltacast video card is replaced by an internally designed card that provides an easily customizable setup (as two IN/OUT channels, an active by-pass, and future HDMI channels);
3. A cosmetic change of the front panel layout and a new keyboard is designed to provide new information by LED indicators (system booting, peripherals check) and the new design also allows the elimination of internal alkali batteries.
4. The internal power supply type is changed to supply a range of potentials instead of needing another board to control it, thus obtaining a direct combination with ATX internal boards and features an internal fuse.
5. The new internal layout allows the reduction of the hardware case height and consequently the replacement of internal fans with smaller ones that are also less noisy and a new shape of the dust filters.

Furthermore, introduction of the NVIDIA IGX Orin™ kit requires the following changes to the software components:

1. Change of GI Genius Operating System 1.0.0 to GI Genius Operating System S ver.1.0.0. The software architecture of the operating system is the same, but the following items are updated:
   - SOUP Ubuntu ver. 22.04 LTS,
   - SOUP CUDA ver.12.2,
   - SOUP cuDNN ver. 8.9.4,
   - SOUP TensorRT ver. 8.6.2,
   - SOUP WebKit ver. 2.44,
   - Internal video card driver SDI Link ver.1.0.0.
2. Rebuilding of software ColonPRO™ 4.0 to create a container ready for the new OS (build identified as ver. 4.0.0-S). Changes to the software made only to allow using the container in the new hardware. No medical performances are changed as effect of rebuilding.

As consequence, the hardware and software design changes will result in a range extension for the hardware models setting up the system with software ColonPRO™ 4.0, with three versions being available, these being:

- GI Genius™ Module 100 (current model with HD capability only, as cleared under K233964)
- GI Genius™ Module 200 (current model with 4K UHD capability, as cleared under K233964)
- GI Genius™ Module 300 (new model with 4K UHD capability and NVIDIA IGX Orin™ kit core unit),

as well as two builds of the ColonPRO™ 4.0 container given by version 4.0.0 (as cleared under K233964) and by version 4.0.0-S (rebuild only for the new hardware model).

The last change is a labeling update to include two additional video processors in the list of compatible units in the User Manuals, namely PENTAX Medical Video Processor EPK-i5500c and EPK-i8020c, for all the three GI Genius™ systems.

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

- Verification of the hardware at the system level. Each functional element of the hardware requirements was tested and found to meet specifications, encompassing 38 hardware requirements.
- Validation of the hardware functions at the user level has been carried out, incorporating tests sufficient for the validation of the hardware requirements specifications.
- Electrical Safety and Electromagnetic Compatibility (EMC) compliance tests have been successfully completed on the hardware unit with the NVIDIA IGX Orin™ kit according to IEC 60601-1 and IEC 60601-1-2 requirements, operating with software build 4.0.0-S.
- Verification of the software build at the system level. Each element of the SRS was tested and found to meet specified requirements, testing 36 Units and 24 Items, encompassing 176 software requirements.
- Validation of the new software build at the user level has been carried out, incorporating tests sufficient for the validation of the SRS.
- Risk mitigation measures identified during Risk Management have been successfully verified or validated, as applicable.
- Tests according to the Standalone Performance Testing Protocol v2.0, submitted as part of the K233964 predicate device submission, have been repeated for the applicable parts of the subject device.
- Non-inferiority of performance of GI Genius™ systems with two new video processors has been established by means of a per-frame assessment on 40 pre-recorded procedures from each video processor.

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

Substantial equivalence:
The predicate devices for the subject devices are the pre-modification versions of the same devices, GI Genius™ Module 100 and GI Genius™ Module 200, FDA-cleared under K233964 on 12 January 2024:

Predicate Devices:	GI Genius™ Module 100 and GI Genius™ Module 200 with ColonPRO™ 4.0
Sponsor:	Cosmo Artificial Intelligence - AI Ltd
De Novo Number:	K233964
Clearance Date:	12 January 2024
FDA Product Code:	QNP
Classification Name:	Gastrointestinal lesion software detection system
Regulation No:	21 CFR 876.1520
Class:	II

Predicate device comparison table:
In terms of addition of two video processors to the list of compatible units to the subject devices given by GI Genius™ Module 100 and GI Genius™ Module 200 with software ColonPRO™ 4.0, the addition of said video processors in the User Manul is the only difference with respect to the predicate devices.

In terms of the hardware and software changes proposed with the new hardware extension given by GI Genius Module™ 300 with software ColonPRO™ 4.0 (build 4.0.0-S), Table 1 reports the comparison to the predicate device.

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

Table 1: Predicate device comparison table

Characteristic	Subject device	Predicate device	Comparison
Device name	GI Genius™ Module 300 (GGM300-US); ColonPRO™ 4.0 (build 4.0.0-S) (CPRO40S-US); GI Genius™ Module 100 (GGM100.US);	GI Genius™ Module 100 (GGM100.US); GI Genius™ Module 200 (GGM200.US) ColonPRO™ 4.0 (build 4.0.0) (CPRO40.US)	Different device name for GGM300-US

Table 1: Predicate device comparison table			
Characteristic	**Subject device**	**Predicate device**	**Comparison**
	GI Genius™ Module 200 (GGM200.US); ColonPRO™ 4.0 (build 4.0.0) (CPRO40.US).		
Manufacturer	Linkverse S.r.l., Italy	Linkverse S.r.l., Italy	Same
FDA clearance	This submission	K233964	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
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	GGM300-US: 29 µs (< 5.75 ms limit) GGM200.US: 0.74 µs GGM100.US: 1.52 µs	GGM200.US: 0.74 µs (< 5.75 ms limit) GGM100.US: 1.52 µs	Equivalent
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	Yes: PENTAX Medical EPK-i5500c PENTAX Medical EPK-i8020c	N/A	Same
Accessories (optional)	GGM300-US: optional not available GGM200.US: optional available GGM100.US: optional available	Footswitch USB K-switch	Optional not available for GGM300-US
Software other function	Procedure Highlights function	Procedure Highlights function	Same
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	Yes, non-functional to user	Yes, non-functional to user	Same

Conclusion

The subject and predicate devices have identical indications for use and fundamental technological characteristics. Any differences in performance between the subject and predicate devices do not raise

different questions of safety and effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate devices, which are already in interstate commerce within the USA. Therefore, the subject devices are as safe and effective as the predicate devices.