January 12, 2024

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

Re: K233964
Trade/Device Name: GI Genius™ Module 100 (GGM100.US); GI Genius™ Module 200 (GGM200.US); ColonPRO™ 4.0 (CPRO40.US)
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: December 15, 2023
Received: December 15, 2023

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,

Shanil P. Haugen -S

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)*

K233964

Device Name

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

510(k) Summary

510(k) Reference:	K233964
Device Name:	GI Genius™ Module 100; GI Genius™ Module 200; ColonPRO™ 4.0.
Type of 510(k) submission:	Special
Date of submission:	15 December 2023
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 K231143.

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 and 200).

GI Genius™ Module 100 and 200 are compatible with Video Processors featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) output ports and endoscopic display monitors featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) input ports. GI Genius™ Module 200 is also compatible with Video Processors featuring the 4K UHD standard.

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 versions of the device that are the subject of this submission.

Design changes:
This Special 510(k) submission describes the design changes incorporated into GI Genius following FDA clearance under K231143. The device software version number as cleared under K231143 was 3.0.2; the device software version that is the subject of this Special 510(k) is 4.0.0 and it is named ColonPRO™ 4.0.

Two types of design change are detailed in this submission. The first covers the planned design changes that fall within the FDA guideline for submittal of a new 510(k), and the second covers the addition of a new software function with no medical purpose that is included given that it has been developed in the same new version of the software. In addition, a labeling change is planned, to include the non-clinical performance data of the new software version and the instructions to visualize the output readings of the software new other function named Procedure Highlights.

The technical specifications are identical between the predicate and the subject devices except for the following software change:

1. New software version ColonPRO™ 4.0 has improved detection performance resulting from the retraining of the neural network. This is the only software change affecting the detection performance.
2. Software items have been updated, without effect on device performance:
   - SOUP Ubuntu ver. 20.04 LTS,
   - SOUP CUDA ver. 11.6,
   - SOUP VideoMasterSDK ver. 6.21,
   - SOUP cuDNN ver. 8.4.1.50,
   - SOUP TensorRT ver. 8.4.3.1,
   - SOUP VPN and SSH service configured with certification-based authentication,
   - SOUP WebKit ver. 2.38.6 for management of interface content,
   - Internal wrapper library to VideoGenius library for communication with video card,
   - GUI Genius for management of common user interface,
   - License Manager for management of software licenses,
   - Docker Manager for management of containers.
3. ColonPRO™ 4.0 has been containerized within the operating system to optimize future deployment of software changes and updates by reorganizing the architecture of the software items. This change does not affect the device performance.
4. ColonPRO™ 4.0 introduces the new non-clinical function Procedure Highlights that provides data to be aggregated and used by healthcare organizations, thus supporting their internal programs on optimization of practices. This other software function is independent with respect to the software detection performance.

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

- Verification of the revised software at the system level. Each element of the SRS was tested and found to meet specified requirements, testing 33 Units and 22 Items, encompassing 162 software requirements.
- Validation of the revised software 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 K231143 predicate device submission, have been repeated for the applicable parts of the subject device.

The results of the above testing aid demonstration of substantial equivalence of the subject device with the predicate device, as the same 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, FDA-cleared under K231143 on 19 May 2023:

Predicate Device:	GI Genius™ System 100 and GI Genius™ System 200
Sponsor:	Cosmo Artificial Intelligence - AI Ltd
De Novo Number:	K231143
Clearance Date:	19 May 2023
FDA Product Code:	QNP
Classification Name:	Gastrointestinal lesion software detection system
Regulation No:	21 CFR 876.1520
Class:	II

Predicate device comparison table:

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 100 with ColonPRO™ 4.0	GI Genius™ Module 200 with ColonPRO™ 4.0	GI Genius™ System 100	GI Genius™ System 200	Different device name
Manufacturer	Linkverse S.r.l., Italy		Linkverse S.r.l., Italy		Same
FDA clearance	This submission		K231143		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	1.52 µs	0.74 µs	1.52 µs	0.74 µs	Same
Lesion-based sensitivity	88.07%		86.5 %		Improved
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: 269,223 True negative: 5,239,128 False positive: 104,669 False negative: 192,567		Improved
True positive rate per frame	Mean: 60.14 % % of polyps: 100 %		Mean: 58.30 % % of polyps: 100 %		Improved
False positive rate per frame	Mean: 1.79%		Mean: 1.96 %		Improved
Frame-Based TPr/FPr ROC curve, AOC	0.826		0.796		Improved
False positive clusters per patient	< 500 ms: 97 > 500 ms: 10		< 500 ms: 106 > 500 ms: 11		Improved
Additional video processor	None		N/A		Same
Accessories (optional)	Footswitch USB K-switch		Footswitch USB K-switch		Same
Software other function	Procedure Highlights function		None		Procedure Highlights is a new software function for internal programs of healthcare organizations only.
Electrical safety	IEC/EN 60601-1		IEC/EN 60601-1		Same
Electromagnetic compatibility	IEC/EN 60601-1-2		IEC/EN 60601-1-2		Same

Table 1: Predicate device comparison table			
Characteristic	**Subject device**	**Predicate device**	**Comparison**
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 device is substantially equivalent to the predicate device, which is already in interstate commerce within the USA. Therefore, the subject device is as safe, as effective, and performs better than the predicate device.