May 19, 2023

Cosmo Artificial Intelligence - AI Ltd
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consluting Srl
Piazza Albania 10
Rome, 00153
ITALY

Re: K231143
Trade/Device Name: GI Genius System 100 and GI Genius System 200
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal lesion software detection system
Regulatory Class: Class II
Product Code: QNP
Dated: April 20, 2023
Received: April 21, 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231143

Device Name
GI Genius System 100 and GI Genius System 200

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.

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510(k) Summary

510(k) Reference:	K231143
Device Name:	GI Genius System 100 and GI Genius System 200
Type of 510(k) submission:	Special
Date of submission:	15 May 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: **Email:**	+39 06 578 2665 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 identical to that for the original unmodified (predicate) device, as cleared under K211951.

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 compatible with Video Processors featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) output ports and endoscopic display monitor featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) input ports.

GI Genius 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.

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 K211951. The device software version number as cleared under K211951 was 2.0.0; the device software version that is the subject of this Special 510(k) is 3.0.2.

Two types of design change are detailed in this submission. The first covers planned design changes that fall within the FDA guideline for submittal of a new 510(k), and the second covers minor design changes incorporated into the design that have been the subject of internal documentation. In addition, a labeling change is planned, to include a 4K UHD video processor in the list of compatible units in the User Manual.

As a result of user requests, optional accessories are planned to be offered for use with GI Genius, these being a footswitch/USB K-switch to operate as follows:

- Footswitch: the GI Genius software overlays on the main display image the markers around the target objects. Such overlaid markers can be switched ON/OFF by the user by means of a button on the hardware unit front panel. The footswitch allows the user to operate the same switching function by foot as an alternative to the button on the front panel.
- USB K-switch: Allows communication between the footswitch and the GI Genius hardware unit, by converting the footswitch signal to a command already recognized by the GI Genius software, which, as a result, does not need to be modified.

A new endoscopy video processor is to be added to the list of video processors that are compatible with the GI Genius, namely the Olympus CV-1500 EVIS X1, which operates in accordance with the 4K UHD standard. The current GI Genius videoboard does not support the 4K UHD standard, so a new videoboard that does support 4K UHD functionality will be sourced and incorporated into the GI Genius that is the subject of this Special 510(k).

Changing the videoboard would normally necessitate a change to the polyp detection AI-based software for the device, so to allow maintenance of the current unchanged software version, the videoboard software communication will be interfaced by a new internal library, working as a 'wrapper'. The wrapper will convert the 4K UHD video stream from the video processor to HD as an input to the GI Genius software, and then convert the GI Genius software screen overlay from HD to 4K in output. Such design allows the original video frames of the endoscopy video processor not to be altered.

With the understanding that many GI Genius users will not require 4K UHD capability, at least for the time being, this design change will result in a range extension for the GI Genius, with two versions being available, these being:

- GI Genius System 100 (the current model, as cleared under K211951, but with new device model name, and ability to use footswitch/K-switch), and
- GI Genius System 200 (the new model with 4K UHD capability, including full 4K UHD compatibility with the Olympus CV-1500 EVIS X1 video processor, and ability to use footswitch/K-switch).

Non-clinical testing:
The following verification / validation activities have been carried out:

- Verification of the revised software at the system level has been carried out, incorporating tests sufficient for the verification of the SRS.
- Validation of the revised software at the user level has been carried out, incorporating tests sufficient for the validation of the SRS.
- Verification of the three new SRS related to the internal library wrapper has been carried out at the system level and found to meet requirements.
- Validation of the new SRS related to the internal library wrapper at the user level has been carried out and a Validation Test Report was generated.
- Risk mitigation measures identified during Risk Management have been successfully verified or validated, as applicable.
- Electromagnetic Compatibility (EMC) and Electrical Safety compliance tests have been successfully completed on the hardware variant with the 4K video board according to IEC 60601-1 and IEC 60601-1-2 requirements, operating with software version 3.0.2.
- Tests according to the Standalone Performance Testing Protocol v2.0, submitted as part of the K211951 predicate device submission, have been repeated for the applicable parts of the subject device.
- As part of the above protocol, non-inferiority of performance of GI Genius with the Olympus CV-1500 EVIS X1 UHD video processor has been established by means of a per-frame assessment on 42 pre-recorded procedures. Since the Olympus CV-1500 simultaneously outputs both HD and UHD video signals, the non-inferiority test has been conducted on the UHD video signal only and on GI Genius System 200 only, as this represents the worst-case condition for compatibility testing.
- The footswitch and the USB K-switch send a single switching command to the GI Genius software to turn ON/OFF the overlay on target objects. The Electromagnetic Compatibility (EMC) and

Electrical Safety compliance tests have been successfully completed on the footswitch and USB K-switch, according to IEC 60601-1 and IEC 60601-1-2 requirements.

- Given that the user interface of the GI Genius system will not change, a usability study has been performed with respect to use of the footswitch and USB K-switch, to verify the acceptability of the risk control measures.

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 DEN200055 on 9 April 2021:

Predicate Device:	GI Genius
Sponsor:	Cosmo Artificial Intelligence - AI Ltd
De Novo Number:	K211951
Clearance Date:	23 July 2021
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 System 200	GI Genius System 100	GI Genius	N/A
Manufacturer	Linkverse Srl, Italy		Linkverse Srl, Italy	Same
FDA clearance	This submission		K211951	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	0.74 µs	1.52 µs	1.52 µs	Improved for System 200 *

Table 1: Predicate device comparison table				
Characteristic	**Subject device**		**Predicate device**	**Comparison**
Lesion-based sensitivity	86.5 %		86.5 %	Same
Frame level performance (150 videos / 338 polyps)*	True positive: 269,223 True negative: 5,239,128 False positive: 104,669 False negative: 192,567		True positive: 269,223 True negative: 5,239,128 False positive: 104,669 False negative: 192,567	Same
True positive rate per frame	Mean: 58.30 % % of polyps: 100 %		Mean: 58.30 % % of polyps: 100 %	Same
False positive rate per frame	Mean: 1.96 %		Mean: 1.96 %	Same
Frame-based TPr/FPr ROC curve, AOC	0.796		0.796	Same
False positive clusters per patient	< 500 ms: 40 less than baseline > 500 ms: 1 more than baseline		< 500 ms: 40 less than baseline > 500 ms: 1 more than baseline	Same
Additional video processor	Yes: Olympus CV-1500 EVIS X1 with UHD output	Yes: Olympus CV-1500 EVIS X1 with HD output	N/A	Same
Optional footswitch	Yes, connected via K-switch to USB port		No	New functionality
Electrical safety	IEC/EN 60601-1 (including footswitch/K-switch)		IEC/EN 60601-1	Same
Electromagnetic compatibility	IEC/EN 60601-1-2 (including footswitch/K-switch)		IEC/EN 60601-1-2	Same
LAN port	Yes, non-functional to user		Yes, non-functional to user	Same

Note *: UHD pixels are 8 times faster that HD pixels. To cope with this increase, 4 parallel processors are used, resulting in a two-fold lower video delay value.

The subject device and the predicate device have many identical or similar characteristics. None of the identified differences introduce new aspects of safety or effectiveness.

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.