July 23, 2021

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

Re: K211951
Trade/Device Name: GI Genius
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: June 18, 2021
Received: June 23, 2021

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211951

Device Name
GI Genius

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.

510(k) Summary

510(k) Reference:	K211951
Device Name:	GI Genius
Type of 510(k) submission:	Special
Date of submission:	18 June 2021
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: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 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 DEN200055.

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 the following Video Processors: Fujifilm VP-7000, Olympus CV-180 EXERA II, Olympus CV-190 EXERA III, Fujifilm VP-4450HD, and Pentax EPK-i7000 Video Processor.

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.

Design changes:
This Special 510(k) describes the design changes incorporated into GI Genius following its FDA clearance under DEN200055. The device software version number as cleared under DEN 2000555 was 1.0.2; the device software version that is the subject of this Special 510(k) is 2.0.0.

The design changes include a single software design change that falls within the FDA guideline for submittal of a new 510(k). A labeling change is also planned, to add non-clinical performance data of the new software version and to include one additional video processor type in the list of compatible units in the User Manual. Other minor design changes have been the subject of internal documentation and are being advised to FDA for information only.

The software design change includes an upgrade to the inference engine to optimize algorithm speed and improve energy efficiency, together with a retraining of the neural network with additional procedure videos, and improved data augmentation, to improve polyp detection capability robustness.

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 14 Units and 9 Items, encompassing 133 software requirements.

- Validation of the revised software at the user level, testing 14 Units and 9 Items, encompassing 133 software requirements.

- Protective measures identified by risk management have been verified during Installation Qualification and Operational Qualification.

- Electromagnetic Compatibility (EMC) and Electrical Safety compliance tests have been completed according to IEC 60601-1 and IEC 60601-1-2 requirements.

- Standalone Performance Testing has been carried out to assess the performance of the subject device in accordance with the same test protocol as that used for the predicate device, the results of which demonstrate substantial equivalence to the predicate device.

- Non-inferiority of performance of GI Genius with a new video processor has been established by means of a per-frame assessment on 40 pre-recorded procedures.

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

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:	DEN200055
Clearance Date:	9 April 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 v.2.0.0	GI Genus v.1.0.2	N/A
Manufacturer	Linkverse Srl, Italy	Linkverse Srl, Italy	Same
FDA clearance	K211951	DEN200055	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

COSMO Pharmaceuticals

Table 1: Predicate device comparison table			
Characteristic	**Subject device**	**Predicate device**	**Comparison**
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	1.52 µs	Same
Lesion-based sensitivity	86.5 %	82.0 %	Improved performance
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: 228,929 True negative: 5,235,682 False positive: 108,115 False negative: 232,861	Improved performance
True positive rate per frame	Mean: 58.30 % % of polyps: 100 %	Mean: 49.57 % % of polyps: 99.7 %	Improved performance
False positive rate per frame	Mean: 1.96 %	Mean: 2.02 %	Improved performance
Frame-Based TPr/FPr ROC curve, AOC	0.796	0.723	Improved performance
False positive clusters per patient	< 500 ms: 40 less than baseline > 500 ms: 1 more than baseline	< 500 ms: Baseline > 500 ms: Baseline	Improved Similar
Additional video processor	Yes: Fujifilm VP-7000	N/A	Improved performance
Electrical safety	IEC 60601-1	IEC 60601-1	Same
Electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	Same
LAN port	Yes, non-functional to user	No	Different

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. Therefore, the subject device is as safe, as effective, and performs better than the predicate device.