April 9, 2021

Cosmo Artificial Intelligence - AI, LTD
% Steven Kradjian
CEO and Principal Consultant
Conventus BioMedical Solutions, Inc.
5414 Oberlin Drive, Suite 130
San Diego, CA 92121

Re: DEN200055
Trade/Device Name: GI Genius
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal lesion software detection system
Regulatory Class: II
Product Code: QNP
Dated: November 28, 2020
Received: November 30, 2020

Dear Steven Kradjian:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the GI Genius, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the GI Genius, and substantially equivalent devices of this generic type, into Class II under the generic name Gastrointestinal Lesion Software Detection System.

FDA identifies this generic type of device as:

> **Gastrointestinal lesion software detection system**. A gastrointestinal lesion software detection system is 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 may contain hardware to support interfacing with an endoscope.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 8, 2020, FDA received your De Novo requesting classification of the GI Genius. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the GI Genius into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the GI Genius can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Algorithm failure leading to: • False positives resulting in unnecessary patient treatment; or • False negatives resulting in delayed patient treatment	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Failure to identify lesions, resulting in delayed patient treatment, due to software/hardware failure including: • Incompatibility with hardware and/or data source • Inadequate mapping of software architecture • Degradation of image quality • Prolonged delay of real-time endoscopic video	Software verification, validation, and hazard analysis Non-clinical performance testing Labeling Electromagnetic compatibility (EMC) Electrical safety, thermal safety, mechanical safety testing
False positive or false negative due to user overreliance on the device	Labeling Usability assessment

In combination with the general controls of the FD&C Act, the gastrointestinal lesion software detection system is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including detection of gastrointestinal lesions and evaluation of all adverse events.
(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:
    (i) Standalone algorithm performance testing;
    (ii) Pixel-level comparison of degradation of image quality due to the device;
    (iii) Assessment of video delay due to marker annotation; and
    (iv) Assessment of real-time endoscopic video delay due to the device.
(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.
(4) Performance data must demonstrate electromagnetic compatibility and electrical safety, mechanical safety, and thermal safety testing for any hardware components of the device.
(5) Software verification, validation, and hazard analysis must be provided. Software description must include a detailed, technical description including the impact of any software and hardware on the device's functions, the associated capabilities and limitations of each part, the associated inputs and outputs, mapping of the software architecture, and a description of the video signal pipeline.
(6) Labeling must include:
    (i) Instructions for use, including a detailed description of the device and compatibility information;
    (ii) Warnings to avoid overreliance on the device, that the device is not intended to be used for diagnosis or characterization of lesions, and that the device does not replace clinical decision-making;
    (iii) A summary of the clinical performance testing conducted with the device, including detailed definitions of the study endpoints and statistical confidence intervals; and
    (iv) A summary of the standalone performance testing and associated statistical analysis.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the gastrointestinal lesion software detection system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes

and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Pramodh Kariyawasam at (301) 348-1911.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Acting Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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