November 19, 2021

Chengdu Wision Medical Device Co., LTD.
% John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth St, NW
Washington, DC 20004

Re: K211326
Trade/Device Name: EndoScreener
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal lesion software detection system
Regulatory Class: Class II
Product Code: QNP
Dated: November 18, 2021
Received: November 18, 2021

Dear John Smith:

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, 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)*

K211326

Device Name

EndoScreener

Indications for Use *(Describe)*

EndoScreener is intended as a stand-alone software for real-time automatic detection of polyps in colonoscopy video stream during the procedure.

Physicians are responsible for reviewing the identified areas of suspect polyps presented by EndoScreener and confirming the presence or absence of a polyp on the evaluation of the colonoscopy image on the monitor and their own medical judgment. EndoScreener is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make or confirm a diagnosis.

EndoScreener is indicated for use by licensed endoscopists who perform colonoscopy in adults. EndoScreener is indicated for use with white light colonoscopy.

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

Changdu Wision's EndoScreener

Submitter

Chengdu Wision Medical Device Co., Ltd.

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Wuhou District

Chengdu, Sichuan, China, 610041

Phone: +86 139-1030-8383

Contact Person: JingJia Liu

Date Prepared: November 16, 2021

Name of Device: EndoScreener

Common or Usual Name: Computer aided detection software for colorectal polyps

Classification Name: Gastrointestinal lesion software detection system

Regulatory Class: Class II (21 CFR 876.1520)

Product Code: QNP

Predicate Device: GI Genius (DEN 200055)

Device Description

The EndoScreener is a computer-assisted detection device for colorectal polyps. EndoScreener takes as input colonoscopy video stream from an endoscopy device, which is analyzed in real-time. The device output consists of blue boxes overlaid onto the colonoscopy images to highlight regions of potential polyp. EndoScreener also has the option to sound an alert to the physicians who perform the colonoscopy when a polyp has been detected. Following detection by EndoScreener, the physician must confirm the EndoScreener findings based on his/her own medical judgment.

Intended Use / Indications for Use

EndoScreener is intended as a stand-alone software for real-time automatic detection of polyps in colonoscopy video stream during the procedure.

Physicians are responsible for reviewing the identified areas of suspect polyps presented by EndoScreener and confirming the presence or absence of a polyp on the evaluation of the

colonoscopy image on the monitor and their own medical judgment. EndoScreener is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make or confirm a diagnosis.

EndoScreener is indicated for use by licensed endoscopists who perform colonoscopy in adults. EndoScreener is indicated for use with white light colonoscopy.

Summary of Technological Characteristics

At a high level, the subject and predicate devices are based on the following same technological elements:

- Both the EndoScreener and the GI Genius use artificial intelligence algorithms to assist clinicians in detecting colon polyps colonoscopy examination.
- Both devices take as input a colonoscopy video stream from an endoscopy device and provide as an output a bounding box that highlights the detected polyps.
- Both devices are used in real-time to aid the clinicians in identifying abnormal lesions.

The following technological differences exist between the subject and predicate devices:

- The subject device uses a customized deep learning model, which is likely to be slightly different from the deep learning model and customization used by GI Genius.

Performance Data

In the nonclinical testing of the subject device included validation of the deep learning algorithm on multiple datasets to evaluate per-image sensitivity and specificity as well as per-polyp sensitivity and AUC. Specifically, performance was evaluated on a dataset of 1,138 consecutive polyp patients with histology confirmation and acceptable performance was obtained. For all assessments performed, the EndoScreener functioned as intended and the polyp detection accuracy observed was as expected. Endoscopic imaging degradation and latency due to the device were also evaluated, with appropriate hardware components, and the software device produced no imaging degradation and ignorable end-to-end latency.

EndoScreener performance was also evaluated in a multi-center, tandem colonoscopy, randomized controlled trial, performed at four United States academic medical centers. The study included 223 patients with screening and surveillance indications, whom were randomized to CADe-routine group and Routine-CADe group for back-to-back colonoscopy procedures. The primary endpoint adenoma miss rate (AMR) was significantly lower in CADe-first group and the 1st pass adenoma per colonoscopy (APC) was higher in the CADe-first group.

Based on the clinical performance as documented in the pivotal clinical study, the EndoScreener has a safety and effectiveness profile that is similar to the predicate device.

Conclusions

The EndoScreener is as safe and effective as the GI Genius. The EndoScreener has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the EndoScreener and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the EndoScreener is as safe and effective as GI Genius. Thus, the EndoScreener is substantially equivalent.