May 8, 2026

IntroMedic Co., Ltd.
% Yujung Lee
Senior Manager
Acts
#920, Gwanggyo Central Biz Tower, 260, Changnyong-Daero,
Yeongtong-Gu, Suwon-Si, Gyeonggi-Do, South Korea
Suwon, 16229
Republic Of Korea

Re: K252617
Trade/Device Name: MiroCam® Capsule Endoscope System
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: Class II
Product Code: NEZ
Dated: April 8, 2026
Received: April 8, 2026

Dear Yujung Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252617

Device Name

MiroCam® Capsule Endoscope System (MC1200-B)

Indications for Use *(Describe)*

The MiroCam® Capsule Endoscope System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age.

The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K252617

510(k) Summary

Prepared on: 2026-04-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Intromedic Co., Ltd.
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Correspondent Contact	Ms. Yujung Lee
Correspondent Contact Email	yj.lee@actslab.co.kr

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	MiroCam® Capsule Endoscope System (MC1200-B)
Common Name	Ingestible telemetric gastrointestinal capsule imaging system
Classification Name	system, imaging, gastrointestinal, wireless, capsule
Regulation Number	876.1300
Product Code(s)	NEZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143663	MiroCam® Capsule Endoscope System	NEZ
K180732	MiroCam® Capsule Endoscope System	NEZ

Device Description Summary

21 CFR 807.92(a)(4)

The MiroCam® Capsule consists of an optical dome, LED Module, imaging and communication module, battery, power supply module, cage pin and cage. The capsule can operate inside that human body for 12 hours and is single-use only. The capsule is enclosed in Ultem 1000, a biocompatible plastic. The dome and the capsule body are boned with a medical grade adhesive HP-121 manufactured by the Hankel Corporation. The surface of the plastic body is gold-plated for signal transmission. Once the capsule construction has been completed, it cannot be disassembled. No calibration process is performed prior to use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The MiroCam® Capsule Endoscope System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age.

The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device (MC1200-B) is technologically and functionally equivalent to the predicate device MC1600-B (K180732). Both systems share the same intended use, core technology (Human Body Communication, HBC), and system architecture.

Technological Comparison

21 CFR 807.92(a)(6)

The differences are limited to frame rate and minor configuration changes in the receiver and software.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject device configuration (MC1200-B with MR2000 and MiroView U Plus+ 1.1) is an updated version of the previously cleared MC1200-B system (K143663). The capsule maintains identical dimensions, materials, optical components, internal circuitry, and communication method (HBC). The receiver has been changed from MR1100 to MR2000, and the software updated from MiroView U 3.0 to MiroView U Plus+ 1.1, both of which introduce user interface improvements without affecting diagnostic function.
These updates do not alter the device's intended use, reception mechanism, safety, or clinical performance. The system continues to deliver equivalent performance in signal reception and data handling, as confirmed in Section 3.
Furthermore, the subject device is technologically and functionally comparable to the predicate device MC1600-B (K180732). While the frame rate differs (3 fps for MC1200-B vs. 6 fps for MC1600-B), this difference does not impact clinical usability or safety. Therefore, the subject device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device.

In conclusion, the Subject device is substantially equivalent to the Predicate devices.