December 4, 2024

CapsoVision Inc.
Zane Liu
Director, Regulatory Affairs
18805 Cox Avenue
Suite 250
Saratoga, California 95070

Re: K242643
Trade/Device Name: CapsoCam Plus (SV-3) Capsule Endoscopy System
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: Class II
Product Code: NEZ
Dated: September 3, 2024
Received: September 3, 2024

Dear Zane Liu:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242643

Device Name

CapsoCam Plus (SV-3) Capsule Endoscopy System

Indications for Use *(Describe)*

The CapsoCam Plus SV-3 capsule endoscopy system is intended for visualization of the small bowel mucosa in adults and children older than two years of age. It may be used as a tool in the detection of abnormalities of the small bowel.

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) #:

510(k) Summary

Prepared on: 2024-11-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	CapsoVision Inc.
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Correspondent Contact	Zane Liu
Correspondent Contact Email	zane.liu@capsovision.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CapsoCam Plus (SV-3) Capsule Endoscopy System
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
K192662	CapsoVision, Inc., CapsoCam Plus (SV-3) Capsule Endoscopy S	NEZ
K211684	Given Imaging Ltd. (Medtronic) PillCam SB3 Capsule Endoscopy	NEZ

Device Description Summary

21 CFR 807.92(a)(4)

The CapsoCam Plus (SV-3) Capsule Endoscopy System is intended for visualization of the small bowel mucosa in adults and children older than two years of age. It may be used as a tool in the detection of abnormalities of the small bowel.

The primary component of the CapsoCam Plus (SV-3) capsule endoscopy system is the eponymous single-use, ingestible capsule that acquires and stores video images in on-board memory while moving through the gastrointestinal tract, propelled by natural peristalsis. It is administered under medical supervision either in-person or remotely under video guidance (available for adult patients only). The capsule is typically excreted within 3 to 30 hours after swallowing. Upon excretion, the patient/authorized caregiver retrieves the capsule using the provided retrieval kit and returns it to the physician (or mails the capsules to the download center in a pre-paid

envelope) where the capsule is processed and data is downloaded.

The system consists of the following hardware components and accessories:
• CapsoCam Plus (SV-3) capsules, which are intended for visualization of the small bowel mucosa.
• CapsoRetrieve (CVR1) Capsule Retrieval Kit, a kit of non-powered tools used for the collection, storage, and transportation of the excreted CapsoCam Plus (SV-3) capsules.
• CapsoAccess (CDAS) Capsule Data Access System, a dock which facilitates download/access of data from the SV-3 capsules.

The system also includes software that is unchanged from K192662.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The CapsoCam Plus SV-3 capsule endoscopy system is intended for visualization of the small bowel mucosa in adults and children older than two years of age. It may be used as a tool in the detection of abnormalities of the small bowel.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The proposed device and predicate device have the same intended use as capsule endoscopy systems for the visualization of the small bowel mucosa. The Indications for Use of the devices are likewise similar. Whereas both devices are indicated for use in adults, the proposed device is also indicated for use in children older than two years of age. Whereas both devices may be administered (i.e., ingested by the patient) in inpatient and outpatient healthcare settings, the proposed device may also be administered in a telemedicine setting for adult subjects. These changes do not alter the general purpose of the device or its function; therefore, they do not constitute a new intended use, and furthermore do not raise different questions of safety and effectiveness. Furthermore, the reference device, which is likewise indicated for use in subjects above the age of two and in telemedicine settings, supports the appropriateness of the use of the proposed device in these conditions.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device represents the incorporation of minor design changes to the cleared predicate device, limited to minor design and packaging changes to the CapsoCam Plus SV-3 capsule, CapsoRetrieve CVR1 Kit, and Capsule Access Data System CDAS. The differences in technological characteristics do not raise different questions of safety and effectiveness, and all necessary testing have been conducted to support the changes.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The CapsoCam Plus (SV-3) Capsule Endoscope System performance testing was conducted per the appropriate FDA Recognized Consensus Standards and required bench testing. The bench testing specifically included 1) verification and validation of hardware changes to confirm that, upon the design changes, these devices continue to meet the applicable product specifications, and 2) transportation and shelf-life testing which demonstrated that, in the updated package configuration, the devices can withstand the labeled transportation and environmental conditions and shelf life. Therefore, the results of these tests support that the proposed device, considering the design changes to the components and packaging, is as safe and as effective as the predicate device for the same intended use.

A human factors evaluation was conducted and supported by real world evidence to demonstrate that there the device can be safely and effectively administered to adult patients in a remote setting.

The results of this testing and analysis support that the changes presented with the proposed device do not raise new questions of safety or effectiveness when compared to the predicate device, and that the proposed device performs as intended.

The clinical evidence provided in the submission include (1) a subgroup analysis of the pivotal study for CapsoCam (K151635), which enrolled both transitional adolescents (n=3, age: 19-21) and adult subjects, (2) an analysis of real world data on the pediatric use of CapsoCam in a pediatric gastroenterology clinic in Australia (n=26, age: 3-18), and (3) a review of the clinical literature on the pediatric use of the reference device and other capsule endoscopes cleared by the FDA indicated for use for in patients 2 years and above. Overall, across the reviewed pediatric clinical case data for CapsoCam specifically, the device functioned as intended in all cases to facilitate diagnostic evaluation, and no adverse events occurred. This is consistent with findings from clinical literature, which suggests that small bowel capsule endoscopes perform similarly in adult and pediatric subjects with respect to both safety (adverse event rate) and effectiveness characteristics (diagnostic yield). This evidence thus supports the use of the device in pediatric patients over two years of age.

The non-clinical test results and clinical evidence support that the proposed device function as intended for its proposed intended use and Indications for Use. These results further support that the proposed device performs at least as well as the predicate devices for the same intended use and confirm that any differences in technological characteristics do not raise different questions of safety or

effectiveness.