



December 19, 2025

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

Re: K252480
Trade/Device Name: CE Deliver (DLV)
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: Class II
Product Code: NEZ
Dated: November 21, 2025
Received: November 21, 2025

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252480

?

Please provide the device trade name(s).

?

CE Deliver (DLV)

Please provide your Indications for Use below.

?

The disposable CE Deliver is a 2.5mm single-sheathed device indicated for transendoscopic delivery to the stomach or duodenum of CapsoCam Plus capsule endoscope (CE) devices. This device is intended for patients who are either unable to swallow the capsule or unable to pass the capsule beyond the pylorus in sufficient time to complete the desired diagnostic evaluation.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) #: K252480

510(k) Summary

Prepared on: 2025-11-28

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	CapsoVision, Inc
Applicant Address	18805 Cox Avenue Suite 250 Saratoga CA 95070 United States
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Correspondent Contact	Mr. Zane Liu
Correspondent Contact Email	zane.liu@capsovision.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	CE Deliver (DLV)
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
K163495	AdvanCE Capsule Endoscope Delivery Device	NEZ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The CapsoVision CE Deliver device is a single use, disposable, non-sterile catheter-based medical device designed to facilitate the transendoscopic delivery of the CapsoCam Plus Capsule Endoscope to the stomach or duodenum. CE Deliver is an accessory to the CapsoCam Plus, and is intended for use in patients who are unable to swallow a capsule endoscope or cannot pass it beyond the pylorus in a timely manner.

The CE Deliver is comprised of a thin, flexible catheter with a Capsule Holder at its distal end and a Handle at its proximal end. The Capsule Holder is detachable from the Handle and Catheter by means of a threaded connector. CE Deliver is designed to be used in conjunction with a standard upper endoscope, through which its flexible catheter is inserted into the endoscope's instrument channel, upon which the Capsule Holder may be threaded onto the distal end. The device enables a user to securely load a capsule endoscope onto the distal Capsule Holder, guide it under direct endoscopic visualization to the desired location within the upper gastrointestinal tract, and then precisely release the capsule. After capsule release, the CE Deliver is retracted along with the endoscope, allowing the

capsule to proceed naturally through the GI tract.

The CE Deliver is compatible with upper endoscopes with an instrument channel diameter of 2.8mm or larger.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The disposable CE Deliver is a 2.5mm single-sheathed device indicated for transendoscopic delivery to the stomach or duodenum of CapsoCam Plus capsule endoscope (CE) devices. This device is intended for patients who are either unable to swallow the capsule or unable to pass the capsule beyond the pylorus in sufficient time to complete the desired diagnostic evaluation.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The proposed CE Deliver has the same intended use as the predicate device. Both devices are transendoscopic delivery devices intended for the delivery of capsule endoscopes to the stomach or duodenum in patients who are either unable to swallow the capsule or unable to pass the capsule beyond the pylorus in sufficient time to complete the desired diagnostic evaluation.

The Indications for Use of the proposed device and the predicate device are highly similar, delineating the same range of functionalities and target patient population. For each device, the capsule endoscopy compatibility considerations are included within the Indications for Use with a comparable level of detail.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The proposed CE Deliver has highly similar technological characteristics to the predicate device, AdvanCE. Both devices are single-use, non-sterile, disposable medical devices designed for transendoscopic delivery of capsule endoscopes. They both consist of a flexible catheter, a three-ring handle, and a detachable capsule holder, and are designed for use with a standard upper endoscope (i.e., within the instrument channel) to facilitate accurate positioning and deployment of the capsule within the upper GI tract. Both devices utilize the same technology - i.e., deployment wire-based "push off" mechanism - to facilitate the deployment of capsules from the capsule holder into the GI tract.

Overall, the fundamental scientific technology and operating principles of the two devices are the same, and the minor differences consist primarily of the design of the capsule holder (i.e., the holder of each device optimizes for its range of compatible capsule endoscopes) and other differences in the implementation of the same basic design. These differences do not raise different questions of safety or effectiveness, as they do not alter the fundamental mechanism of action or introduce new risks.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

CapsoVision has conducted comprehensive non-clinical performance tests on the CE Deliver device, including packaging validation and design verification & validation (V&V) at baseline and after accelerated aging. The tests confirm that the system's design outputs meet requirements, supporting its performance, durability, and safety for its labeled 12-month shelf life.

Overall, the results of the performance tests and assessments of the proposed device support that the CE Deliver is at least as safe and as effective as the predicate device for the same intended use, and confirm that any differences do not raise different questions of safety or effectiveness. The results of these tests therefore support a determination of substantial equivalence.