February 14, 2020

CapsoVision, Inc.
Azimun Jamal
Sr. Director of QA/RA
18805 Cox Avenue Suite 250
Saratoga, CA 95070

Re: K192662
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: II
Product Code: NEZ
Dated: October 10, 2019
Received: October 11, 2019

Dear Azimun Jamal:

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,

*for*
Shanil Haugen, Ph.D.
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192662

Device Name
CapsoCam® Plus (SV-3) Capsule Endoscopy System

Indications for Use *(Describe)*
The CapsoCam ® Plus video capsule system is intended for visualization of the small bowel mucosa in adults. 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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empowering through innovation

# 5. 510(k) Summary:

**Date Prepared:** September 24, 2019

**Manufacturer:** CapsoVision, Inc.
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Saratoga, CA 95070
Phone: (408) 624-1488
Fax: (408) 370-4795

**Contact Person:** Azimun Jamal
Director, Quality Assurance & Regulatory Affairs
CapsoVision, Inc.
Phone: (408) 866-6358
E-mail: azimun.jamal@capsovision.com

**Device Information:**

**Classification:** Class II

**Trade Name:** CapsoCam® Plus (SV-3) Capsule Endoscopy System

**Common Name:** System Imaging, Gastrointestinal Wireless Capsule

**Classification Name:** Ingestible telemetric gastrointestinal capsule imaging system (21 CFR § 876.1300)

**Product Code:** NEZ

**Predicate Device:** CapsoCam® Plus (SV-3) System, 510(k) # K183192, cleared on 04/19/19

**Indications for Use:**

The CapsoCam® Plus video capsule system is intended for visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel

**Device Description**

CapsoCam® Plus (SV-3) capsule is a single-use, ingestible video capsule that acquires and stores video images in on-board memory while moving through the gastrointestinal tract, propelled by natural peristalsis. The patient retrieves the capsule using the provided retrieval kit and returns it to the physician who downloads and reviews the images on a computer. The capsule is typically excreted within 3 to 30 hours after swallowing.

CapsoCam® Plus (SV-3) capsule endoscope is a single-use ingestible capsule system for diagnostic visualization of the adult small bowel. The system consists of the following accessories:

- CapsoCam® Plus (SV-3) capsules, which are intended for visualization of the small bowel mucosa in adults and used as a tool in the detection of abnormalities of the small bowel.
- CapsoView (CVV) software program, which is used to download and view CapsoCam® Plus (SV-3) capsule images and to generate capsule endoscopy reports.

- CapsoAccess (CDAS) Capsule Data Access System, which accesses data from the CapsoCam® Plus (SV-3) capsules.
- CapsoRetrieve (CVR1) Capsule Retrieval Kit, which is used for the collection, storage, and transportation of the excreted CapsoCam® Plus (SV-3) capsules.
- CapsoCloud (CLD), which is a cloud-based software application used to manage procedures and to review and analyze images from the CapsoCam® Plus (SV-3) capsule.

**Software Description and System Requirements**

**CapsoView CVV:**

CapsoView is CapsoVision's proprietary software program used to download and view CapsoCam images and to generate capsule endoscopy reports.

CapsoView® can be installed on a computer that meets the following requirements:

| | | |
|---|---|---|
| **CPU** | **Minimum Required** | **Recommended** |
| | Intel Core i3, 4th generation (for image reviewing and reporting only)<br>Intel Core i5, 4th generation (4+ threads for downloading, reviewing and reporting) | Intel Core i7 Quad-Core, 6th generation (8+ threads for optimal downloading performance) |
| **Memory** | **Minimum Required** | **Recommended** |
| | 4GB | 8GB |
| **Operating System** | **Minimum Required** | **Recommended** |
| | PC: Windows 7 (Service Pack 1) (64-bit)<br>Mac: OS X El Capitan | PC: Windows 10 (64-bit)<br>Mac: macOS Sierra or macOS High Sierra |
| **Display** | **Minimum Required** | **Recommended** |
| | Display Resolution of: 1366x768 for Windows 1280x800 for Mac<br>*For low-resolution monitors, it is not recommended to set Scaling over 100%.* | Display Resolution: 1920x1080 Panel Type: IPS (In-Plane Switching) Color Gamut: 100% sRGB with Delta-E <2 (For maximum color accuracy) |
| **Additional Software** | PDF Reader (e.g. Adobe Reader) | |

**CapsoCloud CLD**

CapsoCloud is a cloud-based software application used to manage procedures and to review and analyze images from the CapsoCam® Plus capsule endoscopy system.

CapsoCloud is a web-based interface that can be accessed on a device that meets the following requirements:

## SYSTEM REQUIREMENTS

1. **Computer**

| | |
|---|---|
| **CPU** | **Recommended** |
| | Intel Core i7 Quad-Core, 6th generation |
| **Memory** | **Recommended** |
| | 8GB |
| **Operating System** | **Recommended** |
| | PC: Windows 10 (64-bit)<br>Mac: macOS Sierra or macOS High Sierra |
| **Display** | **Recommended** |
| | Display Resolution: 1920x1200 Panel Type: IPS (In-Plane Switching) Color Gamut: 100% sRGB with Delta-E <2 (For maximum color accuracy) |
| **Network** | **Recommended** |
| | 25 Mbps, 100ms latency |
| **Chrome** | **Supported Versions** |
| | 75.0.3770 – 79.0.3945 |
| **Additional Software** | PDF Reader (e.g. Adobe Reader) |

2. **Mobile device (iPhone, Android phone, iPad, Android tablet)**
   a. **Procedure management and shipping label generation**

| | |
|---|---|
| **Processor** | **Recommended** |
| | iPhone: A9<br>Android Phone: Qualcomm Snapdragon 425 |
| **Memory** | **Recommended** |
| | 2GB |
| **iOS** | **Supported Versions** |
| | 9.0 and above |
| **Android OS** | **Supported Versions** |
| | 4.1.x and above |

   b. **Video Streaming (iPad)**

| | |
|---|---|
| **Memory** | **Recommended** |

| | |
|---|---|
| | 1.4GB |
| **iOS** | **Supported Versions** |
| | 9.0 and above |
| **iPad Model** | **Recommended** |
| | iPad 6 2018, iPad air 2019, iPad Pro all models |

**Comparison of the Technological Characteristic with the Predicate Device:**
The characteristics of the modified CapsoCam® Plus (SV-3) Capsule Endoscopy System is substantially equivalent to the predicate device based on the indications for use and technological characteristics.

The CapsoCam® Plus (SV-3) capsule endoscopy system that supports the Capsule endoscopy procedure consists of the following:

- CapsoCam® Plus (SV-3) capsules, which is intended for visualization of the small bowel mucosa in adults and used as a tool in the detection of abnormalities of the small bowel.
- CapsoView (CVV) software program, which is used to download and view CapsoCam® Plus (SV-3) images and to generate capsule endoscopy reports.
- CapsoAccess (CDAS) Capsule Data Access System, which accesses data from the CapsoCam® Plus (SV-3) capsules.
- CapsoRetrieve (CVR1) Capsule Retrieval Kit, which is used for the collection, storage, and transportation of the excreted CapsoCam® Plus (SV-3) capsules.

The modified CapsoCam® Plus (SV-3) Capsule Endoscopy System has the following similarities to the predicate device:

- Has the same intended use and Indications for Use
- Uses the same operating principle
- Incorporates the same capsule design
- Incorporates the same materials
- Has the same shelf life
- Is packaged and cleaned using the same material and processes

The modified CapsoCam® Plus (SV-3) Capsule Endoscopy System is different from the predicate system in that it includes a new cloud-based software application to manage procedures and review and analyze images from the CapsoCam capsule.

**Performance Data**
The CapsoCam® Plus (SV-3) Capsule Endoscope System performance testing was conducted per the appropriate FDA Recognized Consensus Standards and required bench testing. The modified CapsoCam® Plus (SV-3) Capsule Endoscopy System was tested for the CapsoCloud Software application related changes including in-vivo testing for the image comparison from the proposed and the predicate software and Image Substantial Equivalence Analysis. No additional testing was performed since no other changes were made to the subject device.

The result of this testing concludes that the material and technological characteristics of the CapsoCam® Plus (SV-3) Capsule Endoscopy System do not raise different questions of safety or effectiveness when compared to the predicate device.

**Note:** Since the material is the same as the cleared device CapsoCam® Plus (SV-3) Capsule Endoscopy System under K183192, no additional testing was performed for the Biocompatibility, EMC or electrical Safety test for the subject device.

**Conclusions:**
The subject and predicate device share the same intended use, Indications for Use, and similar technological characteristics. The differences in technological characteristics do not impact safety or effectiveness and verification and validation data demonstrate that the subject device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device that is currently marketed for the same intended use.