



Food and Drug Administration
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October 21, 2016

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

Re: K161773
Trade/Device Name: Capsocam Plus (SV-3) 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: September 20, 2016
Received: September 21, 2016

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161773

Device Name

CapsoCam Plus (SV-3) Capsule Endoscope 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.

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5.0 510(k) Summary

This traditional 510(k) summary for the CapsoCam Plus (SV-3) Capsule Endoscope System is submitted in accordance with the requirements of 21 C.F.R. § 807.92.

5.1 General Information:

Date: October 21, 2016

Manufacturer: CapsoVision, Inc.
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Registration No.: 3008062894

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CapsoVision, Inc.
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Device Information:

Classification: Class II

Trade Name: CapsoCam Plus (SV-3) Capsule Endoscope System

Common Name: System Imaging, Gastrointestinal Wireless Capsule

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

Predicate Devices: CapsoCam (SV-1) (K151635)

Intended 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 Endoscope System 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. The device is contraindicated in patients:

- Who have known or suspected gastrointestinal obstructions, strictures or fistula

- Who are pregnant
- Who have gastroparesis
- Who have a swallowing disorder

CapsoCam Plus (SV-3) capsule endoscope system is a single-use ingestible capsule system for diagnostic visualization of the adult small bowel. The overall system consists of an ingestible Capsule CapsoCam (SV-3), the CapsoRetrieve® (CVR1) Capsule Retrieval Kit, the CapsoAccess® Capsule Data Access System (CDAS) and the CapsoView® (CVV) software. The capsule contains a panoramic color digital video camera, two silver-oxide watch batteries, white-LED light sources, a laser diode for data download and system-control and nonvolatile flash-memory data-storage electronics.

5.2 Comprehensive Description of the Product:

Optics: The capsule contains four wide-angle optical objectives oriented at 90° intervals around the circumference of the capsule. The four objectives are assembled in a monolithic lens mount with four bores. Each objective has a longitudinal field of view of 74° and a transverse field of view of 162°. Taken together, the four lenses image the 360° circumference of the capsule over a length of 5±1 mm.

Imaging sensor: The four optical objectives produce images on a single custom CMOS image sensor that has four separate pixel arrays. A color filter mosaic produces pixels sensitive to red, green, or blue light respectively.

Multi-chip Package (MCP): molded package containing multiple silicon chips:

- **ASIC:** Includes voltage regulator, RAM, CPU, and dedicated circuitry for functions such as JPEG image compression and motion detection.
- **Flash Memory:** Two chips. The capacity of each chip is 4Gb.

Illumination: 16 independently controlled "white" LEDs. Each LED is an AlGaIn blue LED packaged with a phosphor epoxy in a lead-frame package.

Battery/Switch Pack: Subassembly with two 1.55V SR927W silver-oxide watch batteries and a magnetically-actuated switch that activates the capsule when removed from the package.

Printed circuit board (PCB): All electronic components are soldered onto a rigid-flex PCB that is folded inside the capsule.

Capsule housing: The capsule is cylindrical with hemispheric domes at each end. The capsule is 30.5 mm long and 11.3mm in diameter. The capsule housing comprises two thermoplastic parts joined and sealed with an adhesive.

CapsoCam System Technical Specifications:

Capsule Physical:	
Length:	30.5mm
Diameter:	11.3mm
Weight	3.74g
Optical:	
Field of View:	74° x 360°

Depth of field:	0 – 18mm.
Object resolution:	0.1 mm
Illumination:	16 independently controlled white light-emitting diodes (LEDs).
<u>Capsule image storage format:</u>	
Video format:	JPEG color images
Video resolution:	4 x 288 x 206 pixels
<u>Operational:</u>	
Frame rate:	3-5 fps
Operating time:	15 hours

Upon excretion, the capsule is retrieved by the patient using CapsoRetrieve, a capsule retrieval system. The system includes a strainer, which is placed in the patient’s toilet to retrieve the capsule while passing fecal matter, a cup for rinsing, a magnetic rod for grasping the capsule and a vial for storing and transporting the excreted capsule. The patient then returns the capsule to the clinic, where a technician disinfects the capsule and retrieves the data using the CapsoAccess, Capsule Data Access System (CDAS). The data is transferred to the workstation over the link, shown schematically in Figure 4 under the executive summary, from the capsule to the docking system by a serial interface and to the workstation by a Universal Serial Bus (USB).

The reviewing workstation is a computer with the CapsoView image review software installed. The CapsoView (CVV) software displays the video and employs a variety of image enhancement, video navigation, and image analysis features to facilitate the physician’s diagnosis. The software allows the physician to efficiently annotate individual frames from the video and compile a procedure report.

The battery life for the CapsoCam is approximately 15 hours in order to allow complete imaging of the small bowel. Battery-life data collected during the clinical trial was provided with the predicate device (SV-1-K151635).
Software Description:

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

5.2.1 Software Level of Concern:

The software is determined to be “MODERATE” level of concern. This is unchanged from the cleared device SV-1 K161535. The software does not directly cause, control and/or mitigate hazards that could result in injury to the patient or the operator. The risk of malfunctions of the software that leads to an erroneous diagnosis or a delay in delivery of appropriate medical care is minimal.

5.2.2 Image Review Software

5.2.2.1 System requirements

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

CPU	Minimum Required	Recommended
	Intel Core i3 (for image review and reporting only)	Intel Core i7 Quad-Core (for optimal downloading performance)

	Intel® Core™ i5 (for downloading, review and reporting)	
Memory	For 32-bit Operating System	For 64-bit Operating System
	Minimum 2GB	Minimum 4GB
Operating System	For PC	For Mac
	Windows 7 (Service Pack 1) Windows 8.1 Windows 10 (Recommended for optimal downloading performance)	OS X Yosemite OS X El Capitan
Display	Minimum Required	Recommended
	Display Resolution of: 1366x768 for Windows 1280x800 for Mac	Display Resolution: 1920x1080 Panel Type: IPS (In-Plane Switching) Color Gamut: 100% sRGB with Delta-E <2 (For maximum color accuracy)
Additional Software	Adobe Reader XI	

5.2.2.2 Report Output Format:

Portable Document Format (PDF) and DICOM compatible PDF

5.2.2.3 Features:

CapsoView Software possesses the following features, which are described in detail in the noted sections of CapsoView (CVV) IFU-2757.

- Downloading data and Opening Video File IFU-2757, Section 6
- Adding and Editing Procedure Information IFU-2757, Section 7
- Accessing Full-Screen and Standard-View Modes IFU-2757, Section 7
- Playback Toolbar IFU-2757, Section 7
- Playback Status Bar IFU-2757, Section 7
- Annotation User Interfaces IFU-2757, Section 7
- Generating Capsule Endoscopy Reports IFU-2757, Section 8
- Exporting Images and Videos IFU-2757, Section 9
- Adjusting System Settings IFU-2757, Section 10

5.3 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. A detailed test list is provided on page 10 of this summary.



5.4 Accuracy of the Device

Relevance of SV-1 to SV-3 Clinical performance

CapsoVision conducted three (3) studies to demonstrate the equivalence of the images obtained by the SV-3 to the predicate device (CapsoVision SV-1).

Study 1:

Protocol CVI-006 “Validation of CapsoVision CapsoCam® SV-3 Capsule Endoscopy System”; 49 healthy volunteers were enrolled. All subjects were assessed to the inclusion/exclusion criteria and signed the IRB approved Informed Consent prior to participation. Subjects who ingested the SV-3 CE, were assessed for adverse events, and had videos read by the Principal Investigator. The investigator noted on the CRF any landmarks visualized and if any, pathology found (the pathology may or may not be clinically significant). Of the 49 Intent to Treat Study Subjects, 7 dropped out, yielding a total of 42 Per-Protocol subjects for evaluation. In this protocol, the principal investigator was asked to identify key landmarks, completion of exam, identify any pathologies (whether clinically relevant or not), assess image quality. The results are displayed in the tables below:

Demographics

Age: **Gender:**

Male 25 (53.52%)

Female 17 (40.48%)

Mean	36.85714
Standard Error	1.678093
Median	37.5
Mode	30
Standard Deviation	10.87528
Sample Variance	118.2718
Range	42
Minimum	19
Maximum	61
Sum	1548
Count	42
Confidence Level (95.0%)	3.388977

Diagnostic Quality

Image Diagnostic Quality	Yes	No
	40	2

Small Bowel Complete

Yes	No
41	1

Pathologies Identified (grouped by type)

Pathology	Yes	No
Blood	0	42
Angiectasia	2	40
Ulcer	2	40
Polyp/Mass	0	42
Other	4	38

Of the list above, none of the pathological findings were considered clinically significant.

Overall Image Quality

Landmarks Identified		
	Identified	Not identified
1 st Esophageal	40	3
1 st Gastric	42	0
1 st Duodenal	42	0
1 st Cecal	41	1
Papilla	35	7

Images better than previous generation	Yes	No
	4	38

Study 2: Comparisons of reads of select video clips from the study CVI-006 by Independent Blinded readers.

In this study, the images of landmarks and pathologies were extracted from the complete video into short video clips. These video clips were randomized and sent to independent readers who were blind to the nature of the CVI-006 study. Readers were asked to assess landmark video quality, pathologies identified and subjective questions on video/diagnostic quality. The results are provided in the tables, below:

Consensus Amongst readers with video clips of Landmarks

Landmarks	Consensus
1 st Duodenal	15
1st Cecal/IC Valve	12
None	15

In summary all blinded readers were in consensus with one another regarding the landmark video clips from the original CVI-006 Study.

Consensus agreement on landmark video Quality

Overall Consensus for Readers	N=42
Excellent	26
Good	0
Poor	0
N/A	15
Discordant amongst Readers	1

Consensus agreement on pathologies found in CVI-006

Consensus amongst the independent readers

Pathology	Overall reader Consensus (N=42)
Blood	0
Ulcer	0
Vascular	5
Polyp/Mass	1
Other	2
None	34

Consensus when comparing to the original pathologies identified in CVI-006:

Pathology	Original versus Over-read
Blood	0/0
Ulcer	2/0
Vascular	2/5
Other	4/2
None	34/34

Subjective questions on video Quality

Were Images of Diagnostic Quality	Yes	No
	42	0
Better Diagnostic Quality from Earlier Generation	Yes	No
	25	17

Study 3: From the original SV-1 Study, a total of 40 video clips (both normal (11) and with pathology (29) Consensus agreement was reached in 35 of the clips or 87.5% were in agreement with the landmark or clinical pathology findings. There was 100% agreement between the old and new versions of the software. This comparison agreement was manifested even when there was a lack of consensus manifested in the original SV-1 study results.

Of those video clips with landmarks identified in the original SV-1 study, there was consensus in 10 of 11 clips (90.9%). The discordant finding was identical for all 3 readers when using either the original SV-1 software or the new SV-3 software.

Of those video clips with significant clinical pathology identified in the original SV-1 study, there was consensus in 25 of 29 clips (86.2%). The discordant findings were identical for all 3 readers when using either the original SV-1 software or the new SV-3 software.

Subjective Evaluation Questions

For each video clip presented to the independent blinded readers, each were asked to answer the following questions: In general, the newer SV-3 software (CVV 3.3 US) had a more favorable assessment than the SV-1 software (CVV 2.2) for Image quality

- a. **Video Image Quality** – Readers were asked when comparing the clips side by side if the quality was better than, equal to, or worse than another.
- b. **Clinical Assessment Quality** – Readers were asked; when image quality side by side, to determine a clinical assessment, were they equal or was the quality of one better than the other.
- c. **Ease of Use** – Readers were asked, when comparing the two software versions used for each clip (viewing them side by side) was one version easier than, equal to or more difficult than the other.
- d. **Reviewing Experience**– readers were asked to compare their reviewing experience (viewing them side by side) with each clip (and software version used for each), was their experience better than, equal to, or worse than the other.

Results for Video Image Quality

Of all 40 clips reviewed, using the original SV-1 Software (CVV 2.2) for one image and the newer, SV-3 software (CVV 3.2 US) for the other, reviewers responded as follows for Image Quality:

- 28 (70%) Ranked the SV-3 image as better than the SV-1 image;
- 12 (30%) Ranked both SV-3 image and SV-1 image as comparable;
- 0 (0%) Ranked the SV-1 image as better than the SV 3–image

Results for Clinical Assessment Quality

Of all 40 clips reviewed, using the original SV-1 Software (CVV 2.2) for one image and the newer, SV-3 software (CVV 3.2 US) for the other, reviewers responded as follows for Clinical Assessment Quality:

- 1 (2.5%) Ranked the SV-3 image as better than the SV-1 image;
- 39 (97.5%) Ranked both SV-3 image and SV-1 image as comparable;



- 0 (0%) Ranked the SV-1 image as better than the SV-3 image

Ease of use

Of all 40 clips reviewed, using the original SV-1 Software (CVV-2.2) for one image and the newer, SV-3 software (CCV 3.2 US) for the other, reviewers responded as follows for Software Ease of Use:

- 0 (0%) Ranked the SV-1 software as easier than the SV-3 software;
- 39 (97.5%) Ranked both SV-3 software and SV-1 software as equal;
- 1 (2.5%) Ranked the SV-3 software as easier to use than the SV-1 Software

Reviewing Experience

Of all 40 clips reviewed, using the original SV-1 software (CVV-2.2) for one image and the newer, SV-3 software (CVV 3.2 US) for the other, reviewers responded as follows regarding their reviewing experience:

- 0 (0%) Ranked the SV-1 software as a better reviewing experience;
- 38 (95.0%) Ranked both software versions as the same;
- 2 (5.0%) Ranked the SV-1 software as a worse reviewing experience

5.4 Substantial Equivalence:

The characteristics of the CapsoVision, Inc., CapsoCam Plus (SV-3) Capsule Endoscope System is substantially equivalent to the following currently approved predicate device based on the indications for use, typical clinical use, and operational and fundamental technological characteristics.

- CapsoCam Imaging Systems with the following product information:
 - **510(k) #:** K151635.
 - **Product name:** CapsoCam (SV-1)
 - **Classification:** Class II
 - **Classification Regulation:** 21 CFR § 876.1300
 - **Panel: Gastroenterology:** Urology
 - **Product Code:** 78 NEZ
 - **Common Name:** Capsule Imaging System
 - **Classification Name:** Ingestible Telemetric Gastrointestinal Capsule Imaging System.

5.5 Predicate Device Description: (K151635)

CapsoCam (SV-1) 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.

The CapsoCam (SV-1) capsule endoscopy system components that support the CapsoCam (SV-1) Capsule endoscopy procedure consists of the following:

- CapsoCam (SV-1) 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 images and to generate capsule endoscopy reports.
- CapsoAccess (CDAS) Capsule Data Access System which accesses data from the CapsoCam capsule endoscopes.

- CapsoRetrieve (CVR1) Capsule Retrieval Kit which is used for the collection, storage, and transportation of the excreted CapsoCam capsule.

The CapsoCam SV-1 and the CapsoCam Plus (SV-3) capsule endoscope system have identical indications for use and very similar operating principles.

The substantial equivalence between the CapsoCam Plus (SV-3) Capsule Endoscope System and the predicate device CapsoCam (SV-1) Endoscope System Capsule is provided in a detailed discussion and side-by-side comparison in the substantial equivalence discussion.

5.6 Summary of Technical Differences Between CapsoCam Plus (SV-3) capsule endoscope system and Predicate Device

The differences in technical characteristics between the CapsoCam Plus (SV-3) capsule endoscope system and the CapsoCam® SV-1 are minimal and bear no significance on safety or effectiveness. The hardware changes to the modified device is shown in the table below:

	CapsoCam Plus (SV-3) capsule endoscope system
*Hardware	CMOS Image Sensor
	ASIC with larger frame buffer
	Flash Memory
	Camera field-of-view increased
	LED dies
	Capsule Data Access System (CDAS)
	Capsule startup routine
	Mechanical Design-added internal light pipe and reduced dimple on capsule tip
	PCB and PCBA components
	Magnetically Actuated Switch

The CapsoCam Plus (SV-3) capsule endoscope system is an updated version of the CapsoCam (SV-1) (K151635). Unchanged characteristics include: the intended use; the housing materials and sealing process; the form, fit and function while in contact with the patient; the system architecture; the batteries; the package; the lens; and the illumination system. The implemented design changes are intended to maintain the same clinical function while improving the performance, particularly image quality, and to change the method of data download in the clinic after the capsule is excreted.

To improve image quality, the SV-3 includes a new CMOS image sensor with smaller pixels and more numerous pixels than the sensor in SV-1. In order to compress and save images with more pixels, and to be compatible with the new image sensor, SV-3 includes a new ASIC.

In order to provide a simpler process to clinical users, the way that data is downloaded from the CapsoCam capsule at the clinic after excretion and retrieval has been changed. For SV-1, the capsule's plastic cap is cut open, revealing contact pads that electrically connect to the CDAS1 (CapsoVision Data Access System), allowing the CDAS1 to power the SV-1 and to download the data over an SPI (Serial Peripheral Interface) bus. For SV-3, the capsule does not need to be cut open. The CDAS3 communicates with the capsule optically through the plastic cap and inductively powers the capsule during the data download.

The SV-3 is very similar to the SV-1, with the same basic mechanical design, system architecture, and functionality. Most of the components are identical. The camera and illumination system are essentially the same, but with

improved resolution and efficiency. All the changes are designed to change the method of download or to incrementally improve performance without changing the method of image capture, storage, and presentation. In addition to capsule hardware commonalities, the capsules' indications-for-use, contraindications, specified patient condition and recommended clinical protocol (including bowel prep) are unchanged.

5.7 Summary of Technical Differences Between CapsoView CVV 3.2 and CapsoView 2.2 (K151635) cleared version

CapsoView 3.2 uses an innovative, streamlined user interface to make the image review process simpler and more efficient. Users can choose different viewing modes, adjust playback speed, and generate a capsule endoscopy report from a single screen. The software changes to the modified version is shown in the table below:

	CapsoView CVV-3.2
*Software	GUI design
	New GUI features
	Image processing improvements
	Data-download system
	System architecture: support download-only module, batch transcode and saving DICOM videos from AVI files
	OS: Windows and Mac OS X
	Resolution increase

5.8 CapsoRetrieve Capsule Retrieval Kit:

The addition of the Conformity Assessment Body street address was the only change to the Retrieval Kit Instruction for Use (IFU)

Summary of Bench Testing and In-Vivo Testing

Bench testing

Electrical Safety	
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2	60601-1-2 4 th Ed.: 2010/AC:2014, -Medical electrical equipment, Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-6	Medical electrical Equipment-Part 1-6 General requirements for basic safety and essential Performance-Collateral Standard: Usability.
Biocompatibility	
ISO 10993-1	Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing.
ISO 10993-3	Biological Evaluation of Medical Devices, Part 3: Test for Genotoxicity, Carcinogenicity and Reproductive Toxicity.
ISO 10993-5	Biological Evaluation of Medical Devices, Part 5: Tests for cytotoxicity: in vitro methods.
ISO 10993-10	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity.
ISO 10993-11	Biological Evaluation of Medical Devices, Part 11: Tests for systemic toxicity.
Other	
Bite Test	Verification Test Protocol, CapsoCam® Bite Test # PRO-1401and PRO-2513

Shelf life Test	Shelf-life Test Protocol, SV-3 # PRO-2513
Image Verification	Camera Image Verification Test Protocol # PRO-2504
LED	CapsoCam LED Verification Test Protocol # PRO-2350
Color Correction	Software color correction test per protocol # PRO-1910.
Clinical Validation	Validate the performance of the SV-3 capsule in clinical use # PRO-2497
Battery Life test	Battery Life Test Protocol # PRO-0529

In-Vivo testing

Study	
Clinical Study	Validation of CapsoCam-SV-3 Capsule Endoscopy System Protocol Number: CVI-006

5.9 Conclusion:

Based on the similarities in indications for use, and in functional and operational features as evaluated in both clinical and non-clinical performance testing. The CapsoCam Plus (SV-3) Capsule Endoscope System has demonstrated substantial equivalence to the listed predicate device (CapsoCam-SV-1-K151635). Any differences do not affect the product's safety or effectiveness.

All required testing and analyses were completed on the CapsoCam Plus (SV-3) Capsule Endoscope System to ensure that the device is safe and effective for its intended use.