



Food and Drug Administration  
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Silver Spring, MD 20993-0002

February 9, 2016

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

Re: K151635  
Trade/Device Name: CapsoCam® (SV-1)  
Regulation Number: 21 CFR§ 876.1300  
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System  
Regulatory Class: II  
Product Code: NEZ  
Dated: January 14, 2016  
Received: January 15, 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 yours,

**Benjamin R. Fisher -S**

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)

K151635

Device Name

CapsoCam® (SV-1)

Indications for Use (Describe)

The CapsoCam SV-1 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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## 510(k) Summary

Date: February 5, 2016

This 510(k) summary for the CapsoCam™ (SV-1) is submitted in accordance with the requirements of 21 CFR 807.92

### **General Information:**

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

Registration No.: 3008062894

**Contact Person:** Azimun Jamal  
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CapsoVision, Inc.  
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### **Device Information:**

**Classification:** Class II  
**Trade Name:** CapsoCam™ (SV-1)  
**Common Name:** Capsule Imaging System  
**Classification Name:** Ingestible telemetric gastrointestinal capsule imaging system  
(21 CFR § 876.1300)  
**Predicate Devices:** Given Imaging PillCam™ SB2 (K070475)

### **Intended Use:**

The CapsoCam 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® 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 personal computer (PC). The capsule is typically excreted within 3 to 30 hours after swallowing.



Capsule endoscopy is commonly used in patients with OGIB, including those with iron-deficiency anemia, suspected and known Crohn's disease, and malabsorption syndromes such as celiac disease.

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

The CapsoCam® SV-1 video capsule is a panoramic imaging system which includes a panoramic lens system and a multi-array CMOS image sensor. The CapsoCam® has four side-facing cameras arrayed about the circumference of the capsule that together image a full 360° circumference and capture high-resolution color images of the mucosa.

The CapsoCam® SV-1 acquires video images while moving through the patient's gastrointestinal tract. The frame rate is 5 frames per second (FPS) for each of 4 cameras (20 FPS total) the first two hours, and then decreases to 3 FPS per camera (12 FPS total). The initial frame rate is higher because the capsule moves more quickly in the duodenum than in the jejunum or ileum. Currently available imaging systems have only a single camera on one end of the capsule which tends to view the mucosa obliquely and at a distance through liquid which is not always completely clear. In addition, the mucosal surfaces hidden behind folds are not imaged at all. The panoramic imaging system of the CapsoCam® minimizes the possibility that an area of diagnostic interest will be overlooked.

The rate at which the capsule moves through the upper GI tract is variable. In order to conserve memory and battery power, the capsule compares subsequent frames to detect motion. If little or no motion is detected, the capsule enters a "monitor mode" in which captured images are analyzed for motion and then discarded without further processing or archival storage. Once motion is again detected, the capsule returns to a mode where all frames are processed (e.g. JPEG compression) and stored in flash memory.

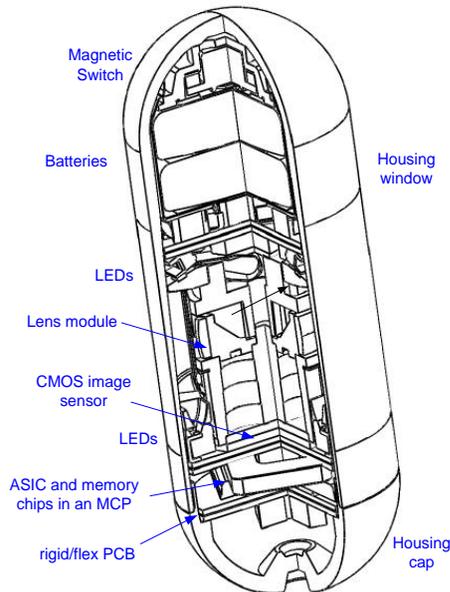
For ease of ingestion (swallowing), the dimensions of the video capsule are as follows:

- Capsule body diameter: 11.3mm
- Capsule body length: 30.5 mm

The materials used in the fabrication of the video capsule housing are Sabic Lexan resin HP1HF, a biocompatible polycarbonate, and Loctite® 3311, an optically-cured acrylated-urethane medical-grade adhesive (USP class VI and/or ISO 10993 compliant).

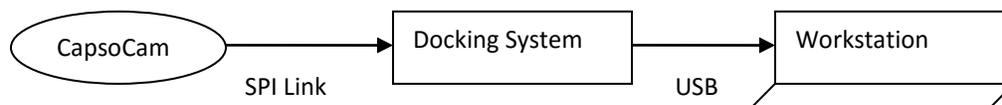
A schematic of the CapsoCam is shown in Figure 3. The capsule housing consists of two injection-molded polycarbonate parts, a "window" and "cap", which are bonded and sealed with a lap joint using the Loctite adhesive. The capsule contains a rigid/flex printed circuit board (PCB) sub-assembly that includes an application-specific integrated circuit (ASIC) and flash-memory

chips in a multichip package (MCP). LEDs are arrayed in two separate rings around the periphery inside the capsule. The imaging system comprises a lens module with four objectives and a single CMOS imaging sensor with four pixel arrays. The capsule includes a battery pack, which includes two silver-oxide batteries and a magnetically actuated switch.



**FIGURE 3: CAPSOCAM™ SCHEMATIC**

After excretion, the capsule is retrieved by the patient using CapsoRetrieve, a capsule retrieval system, including a strainer which is placed in the patient’s toilet to retrieve the capsule while passing fecal matter and rinse water. 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 CDAS is comprised of a capsule carrier for holding the capsule, a capsule opener for cutting off one end of the capsule, and a docking system for forming an electrical contact to the capsule printed circuit board (PCB) through the open end. The data is transferred to the workstation over the link shown schematically in Figure 4 below, from the capsule to the docking system by a serial peripheral interface (SPI) and to the workstation by a universal serial bus (USB).





CapsoAccess Docking Station

<b>CPU</b>	Intel i3 or above. For a faster download speed, an Intel i5 or above is recommended.
<b>Memory</b>	2 GB for 32-bit operating system 4 GB for 64-bit operating system
<b>Operating System</b>	Microsoft Windows XP (with Service Pack 3) Microsoft Windows 7 (with Service Pack 1) Microsoft Windows 8
<b>Display</b>	Minimum display resolution of 1680x1050. Display resolution of 1920x1080 is recommended
<b>Additional Software</b>	Software that is capable of displaying a PDF document on your computer

Work station requirements

**FIGURE 4: CAPSO CAM DOCKING SYSTEM AND WORKSTATION**

The reviewing workstation is a personal computer (PC) 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. Refer to the CapsoView® CVV IFU # 1041 in Section 14 of this submission

CapsoView® presents the four images captured by the four cameras in a row as a panorama.

The size of each quadrant is 128 x 224 pixels so that the total image size is 128 x 896 pixels. CapsoView™ may also be configured to display the quadrants in other arrangements, for example with the first and second quadrants in one row above a second row with the third and fourth quadrants.

The capsule's flash memory has a capacity of 4 gigabits, which is sufficient to store between 32,000 to 50,000 images. The system uses JPEG image-compression technology. The exact number of images that can be stored depends upon the complexity of the image and the compression ratio selected by the bit-rate control. The battery life for the CapsoCam® is approximately 15 hours in order to allow complete imaging of the small bowel. The data for the battery life was collected in accordance with Section 2.2 of the Clinical Study Protocol SV- battery life was defined as total video capture time. Based on the video capture time from the protocol data we have determined the battery life to be approximately 15 hrs. The table below provides the 95% confidence descriptive statistics for the battery life determination from the protocol data set for which the battery life information was available.

Mean	16.5 Hrs.
Standard Error	0.241 Hrs.
Median	16 Hrs.
Mode	16 Hrs.
Standard Deviation	2.39 Hrs.
Range	16 Hrs.
Confidence Level (95.0%)	0.479



❖ **Software Description:**

CapsoView®-CVV software program allows the physician to download the video images from the CapsoCam® capsule through the Capsule Data Access System and to view the images and generate a capsule-endoscopy report.

The software is determined to be “MODERATE” level of concern. 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. The detail for the level of concern conclusion is in document # 0533-Determination of Level of Concern and the details for the risk analyses is in document # 0776-Risk Management File and 0777-Failure Mode and Effect Analyses. Copies of these documents are in Section 19 of this submission.

The CapsoView® software is installed on a personal computer (PC) that meets the requirements stated in the CapsoView® IFU Section 2.1. To install the software, the user logs into the computer as an administrator and clicks the CapsoView® installation wizard program (refer to IFU Section 2.3). The installation wizard program will automatically detect if an old version of CapsoView® has been installed and if any required components are missing. If an old version of CapsoView® is detected, the wizard program can update it to the newer version. If any required component is missing, the wizard program will install that component as well. The CapsoAccess® USB Driver is required to download examination images with the CapsoAccess® Docking System. Instructions for USB driver installation are in CapsoView® IFU Section 2.4. Refer to the CapsoView® CVV IFU # 1041 in Section 14 of the submission.

**Image review software:**

**System requirements:**

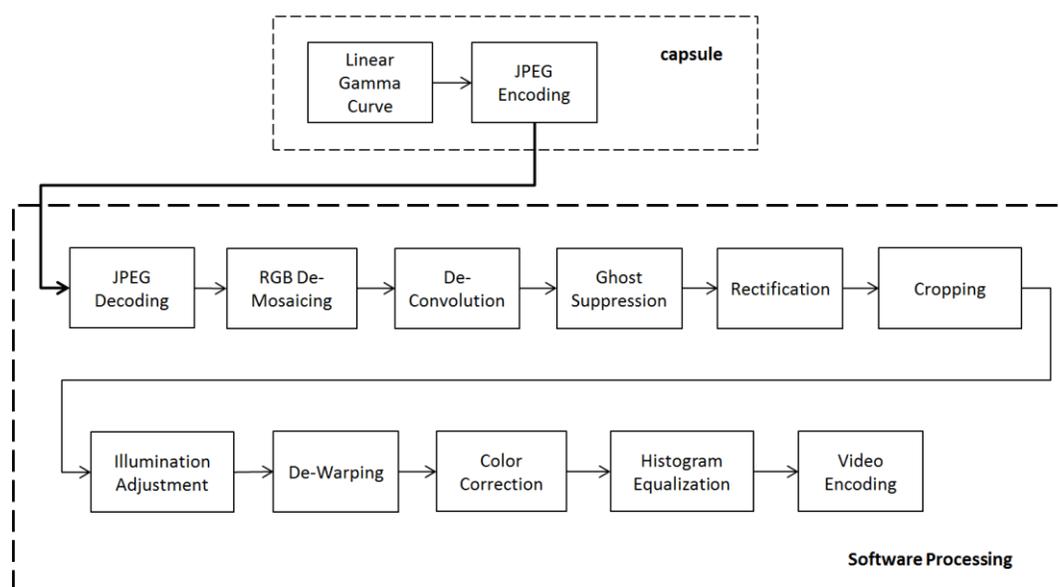
CPU	Intel i3 or above. For a faster download speed, an Intel i5 or above is recommended.
Operating System	Microsoft Windows XP (with Service Pack 3) Microsoft Windows 7 (with Service Pack 1) Microsoft Windows 8
Memory	2 GB for 32-bit operating system and 4 GB for 64-bit operating system
Display	Minimum display resolution of 1680x1050. Display resolution of 1920x1080 is recommended
Additional Software	Software that is capable of displaying a PDF document on your computer

**Report Output Format:** portable document format (PDF)

**Features:** CapsoView Software exhibits the following features:

- Controllable playback.
- Image enhancement processing.
- Image annotation and report generation.

Downloading and image enhancement processing (refer to CapsoView® IFU Section 4): download the compressed JPEG data from the capsule, process the data by applying a series of image enhancement algorithms, and generate an examination video which can be viewed using the CapsoView® software. The image enhancement processing includes the following steps (see the flowchart below): JPEG decoding, RGB de-mosaicking to reconstruct color images from a Bayer pattern single channel image, de-convolution to sharpen the image, ghost suppression to suppress the appearance in the image of scattered LED light reflected from the capsule housing, rectification and cropping to align four camera images based on calibration images, illumination adjustment to correct non-uniformity of the light intensity on all sensor pixels, de-warping to compensate the radial distortion, color correction to improve the color accuracy, histogram equalization to increase the image contrast especially for low-brightness areas, and video encoding to compress the captured frames with x264 video codec.



Review examination video (refer to CapsoView® IFU Section 5): Video is reviewed using two screen modes: standard window with full access to system functions or a full-screen mode with only playback controls. (Refer to CapsoView® IFU Section 5.1.1).

A video can also be reviewed under a normal view or stack view (refer CapsoView IFU section 5.1.2).

There are four cameras in the CapsoCam® capsule endoscope that provide a 360° panoramic view of the gastrointestinal tract. The four images from these four cameras comprise the circumference of the gastrointestinal tract. These four images are displayed in a single row in the normal view mode. In the stack view mode, the images from the four cameras are displayed in two rows, with the first and second images in the top row and the third and fourth images in the bottom row. The stack view mode provides a narrower display width/height aspect ratio.

Playback status information such as the frame number and transit time is also available (refer to CapsoView® IFU Section 5.2). There are many options for playback control, such as play forward, play backward, single frame forward, single frame backward, and use of the keyboard to control the playback. (refer to CapsoView® IFU Section 5.3 for more details).

Annotate images (refer to CapsoView® IFU Section 6): Capture images (refer to IFU Section 6.1) and



make annotation on captured images. All captured images are saved in the image list displayed at the right-hand side of the main screen.(refer to IFU section 6.2).

Text annotation or graphical annotation can be entered (refer to CapsoView® IFU Section 6.3 and 6.4). Annotation can be saved into a separate file in the same folder as the video file (refer to CapsoView® IFU Section 6.5). CapsoView® will automatically load any existing associated annotation file when opening a video.

Generate capsule endoscopy report (refer to CapsoView® IFU Section 7): CapsoView® will generate a PDF capsule endoscopy report using the annotated images selected to be included in the report and all saved comments during the review.

Reference library (refer to IFU Section 8): CapsoView® provides reference images to compare with the images in your videos.

Export video clips and images (refer to CapsoView® IFU Section 9): a segment of the examination video can be saved to a separate file (refer to CapsoView® IFU Section 9.1); an image can also be saved to a separate PNG or JPEG file (refer to CapsoView® IFU Section 9.2).

Change system settings (refer to CapsoView® IFU Section 10): including hospital information, language, mouse, and report information. Refer to the CapsoView® CVV IFU # 1041 in Section 14 of the submission.

### **Performance Data:**

The CapsoCam® Capsule Endoscope System performance testing includes biocompatibility test, electrical safety test, and software life cycle validation to the appropriate FDA Recognized Consensus Standards and bench testing which includes mechanical structural integrity test, pH resistance test, camera imaging test, pull test, coexistence test, battery life test, and battery short-circuit temperature test. The results of this performance testing conclude that the material and technological characteristics do not raise new issues of safety or effectiveness with the CapsoCam (SV-1) Capsule Endoscope System device when compared to the predicate device.

A multi-center, prospective, open-label clinical trial was performed on the CapsoCam® Capsule Endoscope System per Protocol Number SV-1- Comparison of Capso Vision SV-1 to PillCam® SB2 in the Evaluation of Subjects with Suspected Small Bowel Disease. The effectiveness endpoint was to compare the clinical findings involving the small bowel obtained with the CapsoCam® Capsule Endoscope System to those results obtained with the predicate device, PillCam® SB2.

### **Accuracy of the Device**

A clinical study evaluated the performance of the CapsoVision CapsoCam SV-1 compared with the Given Imaging PillCam® SB2 in 121 subjects (age 18 to 85) at 7 Investigational Sites. Downloaded capsule images from both capsule endoscopes were forwarded to independent readers, who were blinded to the subject clinical information or suspected diagnosis. Each set of images, for both capsules, were assessed by a group of three (3) independent readers. Readers reported their findings (Normal, Abnormal, and if Abnormal, the most clinically significant Primary Diagnosis) in the appropriate Clinical Report Forms. If any of the three (3) readers in the group disagreed with the Primary Diagnosis, or complete exam (identified as a capsule that reaches the cecum while still



recording), the findings were discussed by members of the group until a 2/3 majority or consensus agreement for Primary Diagnosis was reached.

The performance of the CapsoVision CapsoCam SV-1 was evaluated based on the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) using the 2 of 3 readers. The PPA was estimated to be 69.05% with lower and upper 95% confidence limits of 53.97% and 80.93%, respectively. The NPA was estimated to be 81.94% with lower and upper 95% confidence limits of 71.52% and 89.13%, respectively.

Concordance of Overall Impression by Capsule  
(Per-Protocol Population) - Majority Agreement

CapsoCam®	PillCam®		
	Abnormal	Normal	Totals
Abnormal	29	13	42
Normal	13	59	72
Totals	42	72	114

Concordance (95% CI)	77.19 (68.68, 83.93)
Positive Agreement (95% CI)	69.05 (53.97, 80.93)
Negative Agreement (95% CI)	81.94 (71.52, 89.13)
McNemar's Test of Agreement p-value	1.0000
Kappa Statistic	0.5099

The Co-Primary endpoint of the study was to compare the percent of CapsoCam® SV-1 completed exams to the PillCam® SB2 in subjects with suspected SB disease. Completed exams were defined as capsules which reach the cecum while the capsule continues recording images. Battery life was to be referenced by video capture time. The number of completed CapsoCam® SV-1 videos to be compared to the number of completed PillCam® SB2 videos and a percentage calculated. The difference in proportion of completed exams was calculated and a 95% confidence interval for correlated proportions was calculated. Non-inferiority was established if the lower confidence limit did not exceed -15%.

The co-primary endpoint was met with a lower two sided 95% confidence limit of -0.028%.

Summary and analysis of capsules that reach the cecum  
(PP Population)

CapsoCam®	PillCam®		Total n (%)
	"Reach the cecum" n (%)	"Did not reach the cecum" n (%)	
"Reach the cecum" n (%)	109 (95.6)	3 (2.6)	112 (98.2)
"Did not reach the cecum" n (%)	1 (0.9)	1 (0.9)	2 (1.8)
Total n (%)	110 (96.5)	4 (3.5)	114 (100.0)

Difference in Proportions of "Reach the cecum" between CapsoCam® and PillCam®	0.018
95% two-sided confidence	-0.028, 0.069



interval for the difference

**Note:** If at least one reader observed the capsule reaching the cecum, the exam would be considered completed.

**Note:** The Newcombe -Wilson score method 10 was used to compute the 95% CI for correlated proportions. In order for the non-inferiority to be established, the lower limit of the 95% CI for the difference of the proportions between the CapsoCam® and PillCam® will have to be greater than -15%

The Secondary endpoint of the study was assessment of the proportion of primary diagnostic yields (normal, vascular lesions, ulcerative lesions, mass/polyp, blood or other) of CapsoCam® SV-1 and PillCam® SB2 in subjects with suspected SB disease based on the result of 2 out of 3 readers in agreement or the consensus group result. Both positive percent agreement (PPA) and negative percent agreement (NPA) were calculated as supportive measures. The table below demonstrates the concordance rate of normal and abnormal, clinically significant primary diagnoses.

Concordance of Primary Diagnosis by Capsule  
(Per-Protocol Population) -Majority Agreement

		PillCam						
		Normal	Vascular	Mass/Polyp	Blood	Ulcerative	Other	Totals
	Normal	57	6	2	2	4	0	71
	Vascular	7	14	1	0	1	1	24
	Mass/Polyp	1	0	0	0	0	0	1
CapsoCam	Blood	0	0	0	1	0	0	1
	Ulcerative	4	1	1	0	9	0	15
	Other	1	0	0	0	0	1	2
	Totals	70	21	4	3	14	2	114

Negative Agreement (95% CI)	[ 57/ 70]	81.43% (70.77, 88.81)
Vascular Positive Agreement (95% CI)	[ 14/ 21]	66.67% (45.37, 82.81)
Mass/Polyp Positive Agreement (95% CI)	[ 0/ 4]	0.00% (0.00, 48.99)
Blood Positive Agreement (95% CI)	[ 1/ 3]	33.33% (6.15, 79.23)
Ulcerative Positive Agreement (95% CI)	[ 9/ 14]	64.29% (38.76, 83.66)
Other Positive Agreement (95% CI)	[ 1/ 2]	50.00% (9.45, 90.55)

Note: All confidence intervals are exact based on the Wilson Score Method.  
Note: Concordance is based on 2 reader agreement or consensus group result.

**Substantial Equivalence:**

The characteristics of the CapsoVision, Inc. CapsoCam® Capsule Endoscope System is substantially equivalent to the following current legally marketed predicate device based on indications for use, typical clinical use, and operational and fundamental technological characteristics.

- Given Diagnostic Imaging Systems marketed by Given Imaging Ltd, with the following product information:
  - **510K #:** K070475.
  - **Product name:** Pill Cam® SB2.
  - **Classification:** Class II.
  - **Classification Regulation:** 21 CFR § 876.1300.
  - **Panel: Gastroenterology:** Gastroenterology - Urology Devices.



- **Product Code:**78 NEZ.
- **Common Name:** Capsule Imaging System.
- **Classification Name:** Ingestible Telemetric Gastrointestinal Capsule Imaging System.

**Predicate Pill Cam Device Description:**

The PillCam® SB2 Capsule is a wireless, disposable video capsule that passes through the GI tract by natural peristalsis. During its passage, the capsule acquires images and transmits them through receiving antennas attached to a belt worn around the waist of the patient.

The PillCam® capsule endoscopy (CE) system components that support the PillCam® capsule endoscopy procedure consists of the following:

- PillCam® capsules, which acquire pictures of the gastrointestinal tract and transmit them to the PillCam® sensors.
- PillCam® recorder connected to the PillCam® sensors, which receives and stores the images collected during the procedure for subsequent video creation with the RAPID software.
- RAPID software, which processes and transforms the raw image data stored in the recorder into a conveniently viewable RAPID video and allows review of the RAPID video.

The CapsoCam® SV-1 and the PillCam® SB2 capsules have the same indication for use and operating principle and are very similar. There are more similarities between the two devices than technological or performance differences.

The substantial equivalence between the CapsoVision CapsoCam® SV-1 Capsule Endoscope System and the predicate device Given Imaging PillCam® SB2 Endoscope System Capsule is provided in a detailed discussion and side-by-side comparison in the substantial equivalence discussion in Section 13 of this premarket notification. In addition, a copy of the summary of safety and effectiveness for Given Imaging PillCam® SB Capsule, 510K # K070475 is provided in Section 22

**Summary of Technical Differences Between CapsoCam and Predicate Device**

The differences in technical characteristics between the PillCam® SB2 and the CapsoCam® SV-1 are not significant. The Pillcam® SB2 uses a single camera at one end of the capsule providing primarily luminal views of the small bowel whereas the CapsoCam® SV-1 uses an array of four cameras and multiple lenses along the circumference providing a 360° lateral panoramic view of the small bowel as the devices progress along the small bowel. The field of view for the CapsoCam® SV-1 is 360° panoramic, whereas the PillCam® SB2 has a field of view of 156°. Similarly, the CapsoCam® SV-1 has a camera imaging frame rate of 3-5 FPS per camera for each of the 4 cameras (a total of 12-20 FPS), and the PillCam® SB2 has a frame rate of 2 FPS.

CapsoCam® SV-1 has a battery life of approximately 15 hours and the Pillcam® SB2, has 8 hours of battery life hours. Both devices employ silver oxide batteries.

**Summary of Bench Testing and In-Vivo Testing**

Bench Testing

<b>Electrical Safety</b>	
IEC-60601-1	Medical electrical equipment - Part 1: General requirements for basic



	safety and essential performance.
IEC-60601-1-2	60601-1-2 Edition 3: 2007-03-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.
<b>Biocompatibility</b>	
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.
<b>Other</b>	
Bite Test	Verification test Protocol, CapsoCam™ Bite Test # PRO-1401.
PH	PH Resistance test per Protocol # 2240.
Optic	Equivalence measurement between PillCam™ and CapsoCam™ per protocol # 1783
LED	LED Measurement per protocol # 2350
Color Correction	Software color correction test per protocol # 1910.
Pilot study	Reference clinical study report section 6.3.
Clinical Study	Clinical study per protocol # Number SV-1- Comparison of Capso Vision SV-1 to PillCam™ SB2.

**In-Vivo testing**

<b>Study</b>	<b>Country</b>
Multi Center Feasibility Study	France
Dual Center Feasibility Study	Germany
Multi Center Pivotal Study	USA

**Conclusion:**

Based on the similarities in indications for use, functional, and operational features as evaluated through clinical and non-clinical performance testing the CapsoVision, CapsoCam® Capsule Endoscope System has demonstrated substantial equivalence to the listed legally marketed predicate device and differences, if any, do not affect the product's safety or effectiveness.

Information described in this 510(k) Summary, all testing and analyses were completed on the CapsoCam® Capsule Endoscope System to ensure that the device is safe and effective for its intended use.