1) 510(k) Summary:

General Information

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Device Information:

Classification: Class II

Trade Name: CapsoCam Plus (SV-3)

Common Name: System Imaging, Gastrointestinal Wireless Capsule

Product Code: NEZ

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

Predicate Devices: CapsoCam Plus (SV-3) System, 510 (k) # K161773), cleared on 10/21/16

1.1 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.

This is the **same intended use** as previously cleared for the CapsoCam Plus (SV-3) under 510(k) K161773, cleared on October 21, 2016.

1.2 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.

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 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.

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).
Capsule image storage format:	
Video format:	JPEG color images
Video resolution:	4 x 288 x 206 pixels
Operational:	
Frame rate:	3-5 fps
Operating time:	15 hours

1.3 Software Description

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

1.3.1 Software Level of Concern:

The software is determined to be "MODERATE" level of concern. This is unchanged from the cleared device CapsoCam Plus (SV-3) K161773. 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. **1.3.2 Image Review Software**

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1.3.2 System requirements

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

CPU	**Minimum Required**	**Recommended**
	Intel Core i3 (for image reviewing and reporting only) Intel Core i5 (4+ threads for downloading, reviewing and reporting)	Intel Core i7 Quad-Core (8+ threads for optimal downloading performance)
Memory	**Minimum Required**	**Recommended**
	4GB (64-bit)	8GB (64-bit)
Operating System	**Minimum Required**	**Recommended**
	PC: Windows 7 (Service Pack 1) Mac: OS X El Capitan	PC: Windows 10 Mac: macOS Sierra or macOS High Sierra
Display	**Minimum Required**	**Recommended**
	Display Resolution of: 1366x768 for Windows 1280x800 for Mac *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)	

1.3.3 Report Output Format

Portable Document Format (PDF) and DICOM compatible PDF

1.4 Substantial Equivalence

The characteristics of the modified 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) #:** K161773.
    - **Product name:** CapsoCam Plus (SV-3) Endoscope System
    - **Classification:** Class II
    - **Classification Regulation:**21 CFR § 876.1300
    - **Panel: Gastroenterology:** Urology
    - **Product Code:** NEZ
    - **Common Name:** Capsule Imaging System
    - **Classification Name:** Ingestible Telemetric Gastrointestinal Capsule Imaging System.

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1.5 Predicate Device Description (K161773)

CapsoCam Plus (SV-3) capsule endoscope 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. The capsule is typically excreted within 3 to 30 hours after swallowing.

The modified CapsoCam Plus (SV-3) has the following similarities to the cleared version CapsoCam Plus (SV-3) 510(k) # K161773), cleared on October 21, 2016:

- Have the same indicated use
- Use the same operating principle
- Incorporate the same capsule design
- Incorporate the same materials
- Have the same shelf life
- Are packaged and cleaned using the same material and processes. and
- The modified CapsoCam Plus (SV-3) capsules have identical indication for use and same operating principles.

1.6 Capsule Data Access System

No design changes were made to the system except for the Instruction for Use (IFU) and a firmware bug fix. Slight modifications were made to the IFU, mainly for formatting and clarification.

1.7 CapsoRetrieve Capsule Retrieval Kit

No design changes were made to the system except for the Instruction for Use (IFU). Slight modifications were made to the IFU, mainly for formatting and clarification and a second source was qualified for the assembly of the retrieval wand without any material change.

1.8 Non-Clinical Testing

The CapsoCam Plus Capsule Endoscope System performance testing includes electrical safety testing, software life cycle validation to the appropriate FDA Recognized Consensus Standards and bench testing which includes LED verification test, Seal Integrity test, Firmware verification test, MCP verification test, Battery life test, Structural, mechanical integrity, camera image test , capsule internal compressive load test, Magnetic field verification test, Shorted battery swelling & force test and Capsule Heating Due to Short Circuit test. The results of this performance testing conclude that the material and technological characteristics of the CapsoCam Plus (SV-3) Capsule Endoscope System device do not raise new issues of safety or effectiveness when compared to the predicate device (K161773).

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1.9 Clinical Summary

System clinical validation testing of the CapsoCam Plus Capsule Endoscope System was performed with healthy human subjects. The testing demonstrated the following:

- Images are captured throughout an entire small bowel exam, with complete small bowel exam defined as the ability of the capsule to reach the cecum while still recording images.
- Images are correctly downloaded using the CapsoAccess® capsule data access system (CDAS3).
- Small bowel images of diagnostic quality are able to be reviewed using the CapsoView® CVV Software and determined to be effective for diagnostic purposes by the study investigator.

The results of this clinical testing demonstrate that it meets the primary endpoints per the study protocol and the performance of the CapsoCam Plus (SV-3) Capsule Endoscope System does not raise new issues of safety or effectiveness when compared to the predicate device (K161773).

2.0 Conclusion:

Based on the similarities in the indications for use, functional, and operational features as evaluated through clinical and non-clinical performance testing the modified CapsoCam Plus (SV-3) Capsule Endoscope System has demonstrated substantial equivalence to the listed cleared version device (CapsoCam Plus (SV-3) 510(k) 161773) and differences, if any, do not affect the product's safety or effectiveness.

All required testing and analyses were completed on the modified CapsoCam Plus (SV-3) Capsule Endoscope System to ensure that the device is safe and effective for its intended use. The modifications discussed in this submission does not affect the intended use of the device nor alters the fundamental scientific technology of this device.