October 13, 2021

Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Guofang MA
QARA Director
No.1 Xinxing Yilu Road, Emerging Industrial Cluster Area,
Zonghan Subdistrict
Cixi, Zhejiang 315300
China

Re: K210116
Trade/Device Name: Video Endoscopy System & 3D Video Endoscopy System
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET, GCJ, FGB
Dated: August 31, 2021
Received: September 7, 2021

Dear Guofang MA:

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,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210116

Device Name
Video Endoscopy System &3D Video Endoscopy System

Indications for Use *(Describe)*
The Video Endoscopy System &3D Video Endoscopy System are intended to be used to provide illumination and visualization of surgical field in a wide variety of diagnostic and therapeutic abdominal and thoracic minimally invasive procedures, including female reproductive organs (gynecology) and urological anatomy.

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.

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Section III 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

3.1 Submitter Information

- **510(k) Submitter/Holder:**
  Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
  No.1 Xinxing Yilu Road, Emerging Industrial Cluster Area, Zonghan Subdistrict, Cixi City, Zhejiang, China

- **Contact**
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- **Date Prepared: October 12, 2021**

3.2 Device Information

Trade/Proprietary Name: Video Endoscopy System & 3D Video Endoscopy System
Common Name: Video Endoscopy System
Models: EVS100, LPS21000, LPS21030, EVS200, LPS31000, LPS31030
Classification Name: Gynecologic laparoscope and accessories
Classification Regulation: 21 CFR 884.1720
Product Code: HET, GCJ, FGB
Device Class: Class II

3.3 Predicate Device

510(k) Number: K150525
Trade/Device Name: SPIES 3D System
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: Class II
Product Code: HET, GCJ, FGB
Manufacturer: Karl Storz Endoscopy-America, Inc.

Proposed device		Predicate device (K150525)
Video Endoscopy System / 3D Video Endoscopy System	Video Endoscopy Processor, EVS100, EVS200	IMAGE1 SPIES
	Video Endoscope，LPS21000, LPS21030 LPS31000, LPS31030	3D TIPCAM®1

The predicate device has not been subject to a design related recall.

3.4 Device Description

The proposed Video Endoscopy Systems include the Video Endoscopy System and 3D Video Endoscopy System, Video Endoscopy System supports 2D image output, 3D Video Endoscopy System supports 2D/3D image output.

Video Endoscopy System is composed of Video Endoscope (LPS21000/LPS21030) and Video Endoscopy processor (EVS100).

Name		Model
Video Endoscopy System	Video Endoscopy Processor	EVS100
	0° Video Endoscope	LPS21000
	30° Video Endoscope	LPS21030

The Video Endoscopy Processor is a video processor, which receives the electrical signals from the Video Endoscope and process it and output the final image to the monitor. Two models 2D Video Endoscope (LPS21000/LPS21030) are available, one image sensor is located at the distal of the endoscope (LPS21000/LPS21030), they are used in conjunction with Video Endoscopy Processor (EVS100) to output 2D images.

3D Video Endoscopy System is composed of Video Endoscope (LPS31000/LPS31030) and Video Endoscopy Processor (EVS200).

Name		Model
3D Video Endoscopy System	Video Endoscopy Processor	EVS200
	0° Video Endoscope	LPS31000
	30° Video Endoscope	LPS31030

The Video Endoscopy Processor is a video processor, which receives the electrical signals from the Video Endoscope and process it and output the final image to the monitor. Two models 3D Video Endoscope (LPS31000/LPS31030) are available, two image sensors are located at the distal of the endoscope (LPS31000/LPS31030), they are used in conjunction with Video Endoscopy Processor (EVS200) to output 2D/3D images.

Video Endoscopy processor is non-sterile device. The Video Endoscope is terminally-sterilized device. The Video Endoscope must be sterilized by users before being used in surgery.

This device is intended to be used in the hospital environment, such as surgical operation room.

3.5 Indications for use

The Video Endoscopy System & 3D Video Endoscopy System are intended to be used to provide illumination and visualization of surgical field in a wide variety of diagnostic and therapeutic abdominal and thoracic minimally invasive procedures, including female reproductive organs (gynecology) and urological anatomy.

3.6 Comparison of the technological characteristics

Table 1 Comparison of subject and predicate device technological characteristics

Comparison Items	**Predicate Device**	**Proposed Device**	**Remark**
product Name	SPIES 3D System	Video Endoscopy System & 3D Video Endoscopy System	/
Regulation No.	21 CFR 884.1720	21 CFR 884.1720	Same
Classification	II	II	Same
Product Code	HET, GCJ, FGB	HET, GCJ, FGB	Same
Indications for Use	3D TIPCAM®1: The Rigid Video endoscope is intended to be used together with the camera control unit is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavity, including gynecological and urological anatomy. IMAGE1 SPIES is a camera control unit (CCU) for use with camera heads or video endoscopes for the	The Video Endoscopy System & 3D Video Endoscopy System are intended to be used to provide illumination and visualization of surgical field in a wide variety of diagnostic and therapeutic abdominal and thoracic minimally invasive procedures, including female reproductive organs (gynecology) and urological anatomy.	Same

	visualization and documentation of endoscopic and microscopic procedures.		
Design	The 3D TIPCAM®1 is connect with IMAGE1 SPIES (CCU) and external light source for uniform illumination of the surgical field, a high-resolution optical system captures the signals from the surgical field and converged it into CMOS. The CMOS converts optical signals into electrical signals, electrical signals are transmitted through electronic devices and converted into video signals, after image processing, video signal is displayed on the monitor, and endoscopic surgery is performed under the guidance of images displayed on a video monitor. **Need external light source.**	The distal end of the endoscope is equipped with white LEDs for uniform illumination of the surgical field, a high-resolution optical system captures the signals from the surgical field and converged it into CMOS. The endoscopic front-end CMOS converts optical signals into electrical signals, electrical signals are transmitted through electronic devices and converted into video signals, after image processing, video signal is displayed on the monitor, and endoscopic surgery is performed under the guidance of images displayed on a video monitor. **Built-in LED light source and heat dissipation**	Different
Resolution	1920X1080 HD	1920X1080 HD	Same
Direction of view	0° , 30°	0° , 30°	Same
Field angle	90°	90°	Same
Depth of field	20 to 200mm	20 to 120mm	Same
Outer diameter of distal end	10mm	LPS21000/ LPS21030:10mm LPS31000/ LPS31030:10.2mm	/
Working length	317mm, 320mm	LPS21000/ LPS21030: 345.5mm, 348.2mm LPS31000/ LPS31030: 338mm, 344mm	Different

Compared with predicate, the proposed devices use built-in LEDs light source instead of external light source and have different working length. The non-clinical testing demonstrates that the differences in technological characteristics between the subject and predicate do not raise different questions of safety and effectiveness.

3.7 Testing

Non-Clinical Testing

The Video Endoscopy System and the predicate device are substantially equivalent in design concepts, technologies and materials. The Video Endoscopy System has been designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

Video Endoscopy System is tested according to the following standards:

- IEC 60601-1:2005, MOD
- IEC 60601-1-2:2014
- IEC 60601-2-18:2009
- ISO 10993-5, 2009 (Cytotoxicity)
- ISO 10993-11, 2010 (Acute Systemic Toxicity & Pyrogen)
- ISO 10993-10, 2010 (Sensitization and Irritation)

Additional bench testing for performance verification and validation purposes:

- Resolution
- Brightness
- White Balance
- 3D-2D Mode
- Color Performance
- Field of View
- Geometric Distortion
- Signal-to-Noise Ratio (SNR) and Dynamic Range
- Image Intensity Uniformity (IIU)
- Photobiological Safety per IEC 62471:2006

The Software Validation is in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Biocompatibility testing supports the device is not toxic, irritating or sensitizing. The device met all acceptance criteria for optical performance testing and was shown to have equivalent image quality to the predicate.

The list of non-clinical test performed on the proposed device.

No.	Test Name

1	System Performance Verification Test
2	Package Verification Test according to ISTA 2A-11&ASTM D 4169-16
3	Sterilization validation according to ISO 17665-1

Clinical Testing

Clinical studies were not required to demonstrate the substantial equivalence of the Video Endoscopy System and the predicated device.

3.8 Determination of substantial equivalence

The subject and predicate devices are both indicated for endoscopic observation during diagnostic and/or therapeutic procedures within the abdominal and thoracic cavities, including gynecological and urological anatomy; there is no difference in the intended use. The differences in technological characteristics between the subject and predicate do not raise different questions of safety and effectiveness. The non-clinical testing demonstrates that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate.