July 8, 2021

270Surgical Ltd.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, PA 19103

Re: K210104
Trade/Device Name: SurroundScope System
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET, GCJ
Dated: June 8, 2021
Received: June 8, 2021

Dear Janice M. Hogan:

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 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)*
K210104

Device Name
SurroundScope System

Indications for Use *(Describe)*
The SurroundScope System is designed to be used with documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities, including the female reproductive organs.

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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K210104
510(k) Summary
270Surgical Ltd.'s SurroundScope System

1. Submitter's Identification

270Surgical Ltd.
P.O.B 8414, 4 Arie Regev St.
Netanya, Israel, 4250212
Phone: +972-509911918
Contact Person: Meital Yogev

Date Prepared: July 6, 2021

2. Name of Device

Name of Device: SurroundScope System
Common or Usual Name: Gynecologic Laparoscope and Accessories
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET (Laparoscope, Gynecologic (And Accessories))
Additional Product Code: GCJ (Laparoscope, General & Plastic surgery)

3. Predicate and Reference Device Information

Predicate: K190190, 270Surgical, WV1 Endoscope
Reference: K151011, Olympus Medical Systems Corp., VISERA 4K UHD SYSTEM Endoscopic Imaging System.

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

4. Device Description

The SurroundScope System (SS) is an endoscopic platform for visualization during surgery. The SS System is a modification of the previously cleared WV1 Endoscope (K190190) developed by 270Surgical. The SS System is designed to be used with documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment. The SS System features two viewing capabilities: standard and extended. The standard view uses one lens and displays a 90 degree field of view while the extended view uses two additional lenses on the side of the tip and displays a 270 degree field of view. Each lens has its own set of LEDs for illumination.

The SS System is comprised of two main components:

- SS endoscope (Video endoscope)
- Camera Controller Unit (CCU) (Video Processor)

<u>SS Endoscope:</u>

The SS endoscope is a reusable, rigid video endoscope.

It is a reusable (autoclavable) endoscope and is intended to be used in a sterile environment. It is initially supplied non-sterile to the user and requires the user to process (i.e., clean and sterilize) the device for initial use, as well as to reprocess the device after each use.

The SS endoscope main components are the video and illumination system, the endoscope body, and the endoscope main connector. The endoscope consists of a camera head at the distal tip, insertion tube, control handle, umbilical cable, and main connector. The insertion tube and distal tip are made of gold coated stainless steel. The distal tip contains sapphire for the optical components. The required illumination for the endoscope is supplied by integrated LEDs, located on the endoscope's distal tip. The endoscope video system is controlled by the video processor which collects the video signal produced by the image sensors (CMOS).

SS System Video Center (CCU)

The SurroundScope Camera Control Unit (CCU) processes and manages the images/video signal from the endoscope and transfers them to the monitor. The CCU video center also powers and controls the CMOS located in the SS endoscope.

5. Indications for Use

The subject device SurroundScope and predicate device K190190 have similar intended use and indications for use (IFU) as follows:

SurroundScope System (K210104) IFU statement:
"The SurroundScope System is designed to be used with documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including the female reproductive organs.

WV1 Endoscope (K190190) IFU statement:
"The WV1 endoscope is a reusable, rigid, video endoscope, designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including the female reproductive organs."

Both the subject device and predicate device are intended for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including the female reproductive organs. Both systems also support the use of documentation equipment, hand instruments, electrosurgical unit, and other ancillary equipment during the same procedures.

Both the subject and predicate devices include an endoscope as their main component. The subject device includes a system comprised of the endoscope and the CCU video system, as in the reference device VISERA 4K UHD SYSTEM cleared under K151011, which was cleared with an endoscope and a video processor unit. This difference does not represent a new intended use or indications for use.

6. Summary of Technological Characteristics and Comparison

The clinical set-up, mode of operation, ergonomics and dimensions of the subject device are similar to the predicate device, 270Surgical's WV1 Endoscope (K190190). Like the subject device, the WV1 Endoscope's main components are the Video endoscope connected to a video processor. The endoscope itself is comprised of the video system, the endoscope body, and the endoscope main connector. In both devices, the required illumination for the endoscope is located on the endoscope's distal tip, and the video signal is produced by the image sensors. The video signal in the subject device is produced by CMOS (Complementary

Metal Oxide Semiconductor) image sensors, while the predicate device's distal tip is equipped with a color CCD (Charge Couple Device).

The primary difference between the subject and predicate device is the output resolution, depth of field, image sensor type, and the video system. These differences in technological characteristics do not raise different questions of safety and effectiveness. A substantial equivalence table, which summarizes the similarities and differences between the SS System and its predicate device, is included below (**Table VI-1**).

Parameter	K210104 – 270Surgical SurroundScope System [Proposed Device]	K190190 – 270Surgical WV1 Endoscope [Predicate]
Indication for Use	The SurroundScope System is designed to be used with documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities, including the female reproductive organs.	The WV1 endoscope is a reusable, rigid, video endoscope, designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including the female reproductive organs.
Class	II	
Regulation	21 CFR§ 884.1720	
Code	HET	
Additional product code	GCJ per 21 CFR §876.1500	
Method of Operation	The optical image is transferred from the surgical site to the camera head.	
Imaging System	Electronic	
Field of View	90º ± 10°/ 270 º ± 10°	
Depth of Field (DOF), Front	17-200 mm	12-175 mm
Direction of view	0º, 90º, -90º	
Articulation	No	
Irrigation	No	
Illumination	Integrated LED	
Illumination fibres	No	
Coupling Lens	No	
Diameter	10 mm	
Working length	340 mm	

Parameter	K210104 – 270Surgical SurroundScope System [Proposed Device]	K190190 – 270Surgical WV1 Endoscope [Predicate]
Eyepiece	No	
Optical System	Color	
No. of Image sensors	3 sensors	
Output resolution	4K (2160p) and HD (1080p)	HD (1080p)
Sterilization	Autoclave	
Control Handle	Buttons on handle	
Video System	CCU by 270Surgical	Fuse Box Processor (K13289)
Max power	400 VA max	250 VA max
Digital video outputs (display)	3 x 3G SDI (1080p) 1 x 12G SDI (2160p)	3 x DVI (1080p)
Video processor Weight	4.5 [kg]	9.5 [kg]
Video processor Dimensions	318 x 93 x 450 [mm]	380 x 450 x 170 [mm]
Operating Ambient temperature	5 to 35 °C (41 to 95 °F)	10 to 35 °C (50 to 95 °F)
Operating Relative humidity	30 to 85 % Atmospheric	
Operating Atmospheric pressure	700 to 1060 hPa	
Storage Temperature	-30 to 60 °C (-22 to 140 °F)	10 to 40 °C (50 to 104 °F)
Storage Relative humidity	30 to 75 %	
Transport Temperature	-47 to 70 °C (-52 to 158 °F)	
Transport Relative humidity	10 to 95 %	
Electric Shock Protection	BF	

Table VI-1: Comparison Table

7. Summary of Performance Data

Bench testing was performed per the following voluntary performance standards or FDA guidance:

Sterilization, Cleaning: Cleaning, drying and sterilization validations were conducted for the SS System, according to AAMI TIR12: 2010, AAMI TIR30: 2011/(R)2016, and ISO 17665-1: 2006. Reprocessing validation was carried out in accordance with the FDA Guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff* (March 17, 2015).The studies were performed by an independent lab, Wuxi AppTec. These tests demonstrated that the device successfully passed cleaning, drying and sterilization validations according to the instructions in the product Reprocessing Manual. The optical resolution was also evaluated after multiple reprocessing cycles to demonstrate the specifications were still met after reprocessing.

Biocompatibility Testing: Biocompatibility testing was performed in accordance with the FDA Guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process"* (September 4, 2020) for an external communicating device in contact with tissue for a limited duration, as follows:

i. Cytotoxicity (ISO 10993-5:2009)
ii. Sensitization (ISO 10993-10:2010)
iii. Irritation (ISO 10993-10:2010)
iv. Acute Systemic Toxicity (ISO 10993-11: 2017)
v. Material-Mediated Pyrogenicity (USP <151>)

All tests demonstrated that the device is biocompatible for its intended use.

Electrical Safety and Electromagnetic Compatibility: testing were conducted according to IEC 60601-1:2005/(R)2012 and A1:2012, (3rd Ed. + AM1), IEC 60601-1-2: 2014, 4th Edition, and IEC 60601-2-18:2009 (Third Edition) that demonstrated electrical safety and electromagnetic compatibility of the subject device.

Software validation: The subject device software was validated per the FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005) based on a moderate level of concern.

Bench Testing:

- **Optical Performance**: Optical testing was done to verify field of view, depth of field, direction of view, signal-noise ratio, non-uniformity, and distortion, according to ISO 8600-1: 2015, ISO 8600-3: 2019; and ISO 8600-5: 2005. Optical comparative testing to the predicate device was done using the same methods to demonstrate equivalent optical performance.
- **Photobiological Safety**: Testing was conducted according to IEC 62471:2006 that demonstrated photobiological safety for the subject device.
- **Color accuracy**: Color testing was done according to the following standards:
    - CIE ISO 11664-1:2019 Colorimetry - Part 1: CIE standard colorimetric observers
    - CIE ISO 11664-2 S 014-2/E First edition 2007-10-15 Corrected version 2008-11-01 Colorimetry - Part 2: CIE standard illuminants
    - CIE ISO 11664-3 First edition 2019-06 Colorimetry - Part 3: CIE tristimulus values
    - CIE ISO 11664-4 First edition 2019-06 Colorimetry - Part 4: CIE 1976 L*a*b* colour space

  - CIE ISO 11664-6 First edition 2014-02-01 Colorimetry - Part 6: CIEDE2000 colour-difference formula
  - CIE ISO 61966-2-1 First edition 1999-10 Multimedia systems and equipment - Colour measurement and management - Part 2-1: Colour management - Default RGB colour space - sRGB [Including: Amendment 1 (2003) and Corrigendum 1 (2014)]
- **System testing**: The overall system was tested for general functionality and latency
- **Dimensional testing:** Dimensional specifications were tested per ISO 8600-1: 2015.

All tests met the predefined acceptance criteria.

8. Conclusions

The SurroundScope System has the same intended use and similar technological characteristics as the predicate device, WV1 Endoscope. Performance testing, including electrical safety, electromagnetic compatibility, cleaning validation, sterilization validation, biocompatibility, and bench testing has demonstrated that the SurroundScope System is as safe and effective as the predicate device. Therefore, the SurroundScope system is substantially equivalent to the predicate device.