November 1, 2019

270Surgical Ltd.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, PA 19103

Re: K190190
Trade/Device Name: WV1 Endoscope
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET
Dated: October 3, 2019
Received: October 3, 2019

Dear Janice 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 Sharon Andrews
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190190

Device Name
WV1 Endoscope

Indications for Use *(Describe)*
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.

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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K190190
510(K) SUMMARY

1. Submitter's Identification

270Surgical Ltd.
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Netanya, Israel, 4250212
Phone: +972-52-8337207
Contact Person: Liat Diamant Porat

Date Prepared: October 31, 2019

2. Device Information

Name of Device: WV1 Endoscope
Common or Usual Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Classification number: CFR §884.1720
Product Code: HET
Additional Product Code: GCJ per 21 CFR §876.1500 [Endoscope and Accessories]

3. Predicate Device Identification

Predicate: K111788, Olympus, EndoEye HD

The predicate device has been subject to a design-related recall.

4. Device Description

The WV1 System is comprised of two main components:

- WV1 endoscope (Video endoscope)
- FuseBox (Video Processor, cleared under (K132839)

The WV1 endoscope is a reusable, rigid, video endoscope.

The device has been designed to be used with a compatible video system, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery.

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 after each use.

The WV1 endoscope main components are the distal tip, the endoscope body and the endoscope main connector. 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 a video signal

produced by the CCD (Charge Couple Device).

The video assembly that controls the field view and image characteristics, including video resolution and brightness, is located in the endoscope's distal tip. The WV1 Distal Tip is equipped with a color CCD and covers a 90° field of view. The extended field of view is achieved by use of additional 2 lenses located behind the endoscope's distal tip, each attached to a separate CCD. The geometrical location of the lenses allows for image overlap that results in the extended field of view (enabled by operation of the Fusebox).

Each view on the distal tip has its own dedicated illumination source (LEDs). The images are presented side by side on a display monitor.

The device materials of the WV1 include SS304, plastics, adhesives and glass lenses. The components are part of an external communicating device in direct tissue contact for a duration ≤24 hours. Although the materials do not conform to a material standard, their biocompatibility was established via testing of the final, finished product.

Environment of use – hospitals and clinics.

5. Indications for Use

The subject device WV1 and predicate device K111788 have identical intended use and indications for use, specifically:

"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 devices are endoscopes designed to be used with a video system to monitor 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.

6. Summary of Technological Characteristics and Comparison

Like the predicate device, the EndoEye HD, main components of the subject device are the Video endoscope connected to a video processor. Similar to most commercially available laparoscopes, the endoscope itself is constructed of a video and illumination 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 CCD (Charge Couple Device).

The principles of operation of the WV1 system are similar to those of other current legally marketed endoscopy systems, although the WV1 System features two viewing capabilities: standard and extended. The operator can extend their mode to extended view at any given time, enabled by operation of the Fusebox.

The primary difference between the subject and predicate device is field of view, direction of view, and light source. The difference in technological characteristics do not raise different questions of safety and effectiveness.

Parameter	K190190 – WV1 Endoscopic Device [Proposed Device]	K111788 – Olympus EndoEye HD II (WA50040A, WA50050A) [Predicate]
Indication for Use	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.	This instrument has been 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 C.F.R. §884.1720	21 C.F.R. §884.1720
Code	HET, GCJ	HET
Method of Operation	The optical image is transferred from the surgical site to the camera head.	
Outer diameter of distal end	The Maximum diameter is 10.7mm and the shaft diameter is 10mm	The Maximum diameter is 10.2mm and the shaft diameter is 10mm
Working length	Working length 340 mm Working channel diameter- N/A. The Endoscope is intended for imaging only. It does not use for other applications that require a working channel.	Working length 325 mm / 330 mm Working channel diameter- N/A. The Endoscope is intended for imaging only. It does not use for other applications that require a working channel.
Video Monitor	N/A (device is not supplied with a monitor)	OEV Series HD Monitor
Light source	Integrated LED Power rating -– not applicable. The WV1 system does not use an external light source.	Xenon short-arc lamp 300W
External Power Supply	N/A	N/A
DOF Depth Of Field	12-175 mm	12-200 mm
Field of View	90º±10 / 270 º±10	90º
Direction of view	0º, -90º , 90º±5%	0°
Type of CCD chip	Color CCD	Color CCD
Number of CCD chip	3	1
Illumination fibers	N/A	Unknown

Parameter	K190190 – WV1 Endoscopic Device [Proposed Device]	K111788 – Olympus EndoEye HD II (WA50040A, WA50050A) [Predicate]
Imaging System	Electronic	Electronic
Eyepiece	N/A	N/A
Coupling Lens	N/A	N/A
Articulation	No	
Autoclave sterilization	Yes	
Control Handle	N/A	Buttons on handle
Compatible Video System	Fuse Box Processor (K132839)	Olympus OTV-S190, Visera Elite Video System Center included in K111788
Ambient Conditions	Operating conditions	
	Ambient temperature	10 to 35 °C (50 to 95 °F)
	Relative humidity	30 to 85 %
	pressure	Atmospheric 700 to 1060 hPa
	Storage conditions	
	Temperature	10 to 40 °C (50 to 104 °F)
	Relative humidity	30 to 75 %
	Transport conditions	
	Temperature	-47 to 70 °C (-52 to 158 °F)
	Relative humidity	10 to 95 %
Electric Shock Protection	BF	BF (WA50040A) CF (WA50050A)

Table VII-1: Comparison Table

7. Summary of Non-Clinical Performance Testing

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

Sterilization, Cleaning:
Cleaning, drying and sterilization validations were conducted for the WV1 Endoscope, according to AAMI TIR12 and AAMI TIR30. The studies were performed by an independent lab. 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). These tests demonstrated that the device successfully passed cleaning, drying and sterilization validations according to the instructions in the product Reprocessing Manual.

Biocompatibility Testing:
Biocompatibility studies were 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", and ISO 10993-1:2009 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: 2014)
v. Material-Mediated Pyrogenicity

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

Bench Testing:

- System test protocol: 270Surgical Ltd. performed Test Protocol (STP) for the WV1 System including the Endoscope, FSP-100 Compatible Video System FUSE by EndoChoice with power cable, monitor and cables. STP included core functionality, image settings screen, LED intensity, zoom feature, system default settings, and white balance feature tests. This STP also includes compatibility testing to verify the WV1 endoscope is compatible to the FSP100 FuseBox console.
- Optical Performance Test: 270Surgical Ltd. verified that WV1 Endoscope field of view, depth of field, direction of view, RMS noise & Signal-noise ratio, non-uniformity, distortion, LED irradiance are according to ISO 8600-1: 2015, ISO 8600-3: 1997; and ISO 8600-5; 2005, IEC 62471: 2006 .
- Heating Test -The objective of this test was to establish the camera head thermal characteristics (°C) in the WV1 endoscope. The test procedure and acceptance criteria were determined according to "Hysteroscopes and Gynecological Laparoscopes Submission Guidance for 510(k) (March 7, 1996)". The acceptance criteria were met.
- 270Surgical Ltd. conducted a user evaluation study to demonstrate that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions in accordance with ANM-0035.

All tests met the predefined acceptance criteria.

8. Conclusions

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