February 24, 2021

Scivita Medical Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.Box 120-119
Shanghai, 200120
China

Re: K203255
Trade/Device Name: 4K UHD Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 25, 2020
Received: December 30, 2020

Dear Diana Hong:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K203255

Device Name
4K UHD Laparoscope

Indications for Use *(Describe)*
The 4K UHD Laparoscope is intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal applications.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# Tab #6 510(k) Summary

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

The assigned 510(k) Number: K203255

1. Date of Preparation: 12/24/2020

2. Sponsor Identification

**Scivita Medical Technology Co., Ltd.**
No. 8, Zhong Tian Xiang, Suzhou Industrial Park, Suzhou, Jiangsu Prov., China.

Establishment Registration Number: Not yet registered.

Contact Person: Ruqin Wu
Position: Quality Manager
Tel: +86-512-81877788
Fax: +86-512-85187285
Email: wuruqin@scivitamedical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd.**
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: +1-360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: 4K UHD Laparoscope
Common Name: Laparoscopes
Model: 4K5500, 4K5500R, 4K5530, 4K5530R, 4K5545, 4K5545R, 4K1000, 4K1000R, 4K1030, 4K1030R, 4K1045 and 4K1045R

Regulatory Information
Classification Name: Laparoscope, General & Plastic Surgery
Classification: II;
Product Code: GCJ / NMH / HET;
Regulation Number: 21 CFR 876.1500 & 21 CFR 884.1720
Review Panel: General & Plastic Surgery

Indication for use:

The 4K UHD Laparoscope is intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal applications.

Device Description:

The 4K UHD Laparoscope is a rigid endoscope, which consists of lighting system and optical imaging system.

The 4K UHD Laparoscope has 12 models which are available in two insertion portion widths (5.5 mm and 10 mm), four working lengths (290mm, 300mm, 320mm and 330mm) and three different directions of view (0°, 30°, 45°). The 12 models are all connected with adaptor 1 and adaptor 2 for different brand source light. The specifications of the proposed device are listed in Table 1.

The 4K UHD Laparoscope can be connected to Scivita 4K UHD Camera System, Scivita LED Light Source or Wolf light source and SONY Monitor. The associated compatible device information is as follows:

| | |
|---|---|
| Endoscope camera system | 4K UHD Camera System, Model: ES-CS4K100/100C and ES-CS4K200/100C (K200216) |
| Scivita light source | Led Light Source manufactured by Scivita, Model: ES-LS110D (510K Exempt, product code: NTN) |
| Wolf light source | Visera 4k UHD Xenon Light Source manufactured by Richard Wolf Medical Instruments Corp., Model: 5123 |
| Monitor | Monitor manufactured by SONY, Model: LMD-X2705MD, |

| | |
|---|---|
| | LMD-X550MD, LMD-X310MD and LMD-X310MT (K150377) |

The 4K UHD Laparoscope is a reusable device that is cleaned and steam sterilized before first use and each subsequent use.

Table 1 Specifications

| No. | Model | Diameter | Working Length | Directions of View |
|---|---|---|---|---|
| 1 | 4K5500 | 5.5 mm | 300 mm | 0º |
| 2 | 4K5500R | 5.5 mm | 290 mm | 0º |
| 3 | 4K5530 | 5.5 mm | 300 mm | 30º |
| 4 | 4K5530R | 5.5 mm | 290 mm | 30º |
| 5 | 4K5545 | 5.5 mm | 300 mm | 45º |
| 6 | 4K5545R | 5.5 mm | 290 mm | 45º |
| 7 | 4K1000 | 10 mm | 330 mm | 0º |
| 8 | 4K1000R | 10 mm | 320 mm | 0º |
| 9 | 4K1030 | 10 mm | 330 mm | 30º |
| 10 | 4K1030R | 10 mm | 320 mm | 30º |
| 11 | 4K1045 | 10 mm | 330 mm | 45º |
| 12 | 4K1045R | 10 mm | 320 mm | 45º |

5. Identification of Predicate Devices

Predicate Device
510(k) Number: K150633
Product Name: “ULTRA” Telescopes
Manufacturer: Olympus Winter & Ibe GmbH
Models: WA4KL100, WA4KL130, WA4KL145, WA4KL500, WA4KL530 and WA4KL545

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 8600-1:2015 Endoscopes - Medical endoscopes and endotherapy devices -- Part 1: General

requirements

- ISO 8600-5:2005 Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics

In addition, the image quality performance tests were conducted to quantitatively compare the proposed device and predicate device in terms of depth of field, geometric distortion, color reproduction and SNR, intensity uniformity, image frame frequency and system delay.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 General Comparison

| ITEM | Proposed Device | Predicate Device K150633 | Remark |
|---|---|---|---|
| Product Code | GCJ / NMH / HET | GCJ / NMH / HET | Same |
| Regulation No. | 21 CFR 876.1500<br>21 CFR 884.1720 | 21 CFR 876.1500<br>21 CFR 884.1720 | Same |
| Class | II | II | Same |
| Indication for Use | The 4K UHD Laparoscope is intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal applications. | These endoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal applications. | Same |
| Single use / Reusable | Reusable | Reusable | Same |
| Feature | Rigid endoscope | Rigid endoscope | Same |
| Mechanism | Viewing Optics | Viewing Optics | Same |
| Principle of operation | During operation, the external light source is transmitted to the front end of the laparoscope through the lighting system of the laparoscope to illuminate the area to be observed. The object is imaged on the imaging system through the objective lens, and then transmitted | During operation, the external light source is transmitted to the front end of the laparoscope through the lighting system of the laparoscope to illuminate the area to be observed. The object is imaged on the imaging system | Same |

| | | | |
|---|---|---|---|
| | to the eyepiece for direct observation by the human eye, or magnified by an external camera system and observed on the monitor. | through the objective lens, and then transmitted to the eyepiece for direct observation by the human eye, or magnified by an external camera system and observed on the monitor. | |
| Outer Diameter | 5.5 mm and 10 mm | 5.4 mm and 10 mm | Different |
| Working Length | 4K5500, 4K5530, 4K5545: 300mm<br>4K5500R, 4K5530R, 4K5545R: 290mm<br>4K1000, 4K1030, 4K1045: 330mm<br>4K1000R, 4K1030R, 4K1045R: 320mm | WA4KL500: 315.3±0.5mm<br>WA4KL530: 315.5±1.5mm<br>WA4KL545: 315.5±1.5mm<br>WA4KL100: 315.9±0.5mm<br>WA4KL130: 317.1±1.5mm<br>WA4KL145: 317.7±1.5mm | Different |
| Direction of View | 0°, 30°, 45° | 0°, 30°, 45° | Same |
| Field of View | 75° | 88° | Different |
| Depth of Field | 3-200 mm | 6-200 mm | Different |
| Patient Contact Material | | | |
| Objective glass cover | Sapphire | Sapphire | Same |
| Optical fiber emission surface | Light Guide fibre | Light Guide fibre | |
| Metal filler | AISI 304 Medical stainless steel | Medical stainless steel | |
| Adhesives | Epoxy resin fiber optic adhesive (Epotek 353ND) | Epoxy resin fiber optic adhesive | |
| Main part | AISI 304 Medical stainless steel | Medical stainless steel | |
| Thermal Safety | IEC 60601-2-18 | IEC 60601-2-18 | Same |
| Biocompatibility | | | |
| Cytotoxicity | Comply with ISO 10993-5 | Comply with ISO 10993-5 | Same |
| Sensitization | Comply with ISO 10993-10 | Unknown | Different |
| Intracutaneous Reactivity | Comply with ISO 10993-10 | Unknown | Different |
| Sterilization | | | |
| Method | Steam sterilization / Low-temperature plasma sterilization | Autoclaved sterilization | Different |
| SAL | $10^{-6}$ | Unknown | Different |

| | | | |
|---|---|---|---|
| Labeling | Complied with 21 CFR Part 801 | Complied with 21 CFR Part 801 | Same |

Different - Outer Diameter

Both the proposed device and the predicate device provide two options for outer diameter. Although the declared size of the outer diameter of the proposed device is not exactly the same as that of the predicate device, the difference is too slight to cause safety and performance issues. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Different - Working Length

Although the working length of the proposed device is not the same as that of the predicate device, the proposed device offers a wider range of options, allowing physicians to make choices based on the patient's condition. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Different - Field of View

Field of view, namely the view of an endoscope with optics, refers to the maximum range that the endoscope can observe at the same time, that is, the cone angle with the vertex at the end of the endoscope head. Although the field of view of the proposed device is different from that of predicate device, it can meet the needs of clinical diagnosis and treatment. In addition, the field of view of the proposed device meets the requirements of ISO 8600-1 with a deviation of not greater than 15%. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Different - Depth of Field

The proposed device has a wider range of depth of field than the predicate device to give physicians more options for diagnosis and treatment based on the patient's condition. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Different – Sensitization and Intracutaneous Reactivity

Although the results of sensitization and intracutaneous reactivity of the predicate device are unknown, the proposed device did both biocompatibility tests. The results showed that the proposed device posed no risk to humans. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Different – Sterilization

Although the sterilization method of the proposed device is different from that of the predicate device, the sterilization verification is performed for the proposed device. The results showed that the Sterility Assurance Level (SAL) reached $10^{-6}$ after steam sterilization and low-temperature plasma sterilization. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.