September 25, 2019

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

Re: K183675
Trade/Device Name: 3D Visualization System
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: GCJ, HET
Dated: August 16, 2019
Received: August 22, 2019

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K183675

Device Name
3D Visualization System

Indications for Use *(Describe)*
This 3D Visualization System is intended to compose the imaging signals from video system center and convert them into 3D signals displayed on the monitor.

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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510(k) Summary: K183675

1. Submitter Information

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Date of Preparation: 9/24/2019

2. Device Information

Trade Name: 3D Visualization System
Models: 3DVS-S100A, 3DVS-S100B, 3DVS-S100C, 3DVS-S100D and 3DVS-S100E
Classification Name: Gynecologic laparoscope and accessories.
Classification: II
Product Code: HET (laparoscope, gynecologic (and accessories)) and GCJ (laparoscope, general & plastic surgery)
Regulation Number: 21 CFR 884.1720
Review Panel: Obstetrics and Gynecology

3. Identification of Predicate Device

Predicate Device
510(k) Number: K123365
Product Name: OLYMPUS LTF-190-10-3D ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE, MAJ-YO154 3D PROCESSOR, OLYMPUS CV-190, EVIS EXERA III VIDEO SYSTEM CENTER

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

4. Device Description

The 3D Visualization System can convert 2D endoscopic images into 3D images synchronously. It is equipped HD-SDI and HDMI outputs ports which are compatible with 3D monitors of various interfaces.

The 3DVS-S100 series 3D Visualization System includes 5 models, which are 3DVS-S100A, 3DVS-S100B, 3DVS-S100C, 3DVS-S100D and 3DVS-S100E. The differences between the models are summarized below.

Table 1. Differences between Each Model

Model	Function	Mode Description
3DVS-S100A	Four imaging modes (1, 2, 3, 4)	Mode 1: single-lens endoscope, enhanced 3D effects Mode 2: single-lens endoscope, standard 3D effects Mode 3: dual-lens endoscope, enhanced 3D effects Mode 4: dual-lens endoscope, standard 3D effects
3DVS-S100B	Two imaging modes (1, 2)	
3DVS-S100C	Two imaging modes (3, 4)	
3DVS-S100D	Two imaging modes (1, 3)	
3DVS-S100E	Two imaging modes (2, 4)	

The 3D Visualization System should be used with the endoscopic image processors which have HDMI or SDI output interface, and the monitors which have SDI, HDMI or DVI interface.

The 3D Visualization System is provided non-sterile and for repeat use. The 3D Visualization System does not have patient-contact and is intended for use by a qualified healthcare professional and is not for home use.

The 3D Visualization System is intended for use in one of two combinations, as summarized in Table 2 and Table 3 below.

Table 2. Combination 1 for proposed device

No.	Device name	Manufacturer	Model	K number
1	3D VISUALIZATION SYSTEM	SCIVITA	3DVS-S100A	/
2	EVIS EXERA Ⅲ VIDEO SYSTEM CENTER (2D Image system)	OLYMPUS	CV-190	K123365

3	ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE (double-lens endoscope)	OLYMPUS	LTF-190-10-3D	K123365
4	EVIS EXERAIII XENON LIHT SOURCE (light source)	OLYMPUS	CLV-190	K121959
5	MONITOR	SONY	LMD-2451MT	K113203
6	3D GLASSES	SONY	TDG-500P	/

Table 3. Combination 2 for proposed device

No.	Device name	Manufacturer	Model	K number
1	3D VISUALIZATION SYSTEM	SCIVITA	3DVS-S100A	/
2	Endoscopic Video Imaging System/Component (2D Image system)	STORZ	Image 1 SPIES	K131953
3	Rhino-Laryngoscope (single-lens endoscope)	STORZ	11101VP	K072387
4	KARL STORZ XENON LIGHT SOURCE MODEL 201320-20	STORZ	201320-20	K934559
5	MONITOR	SONY	LMD-2451MT	K113203
6	3D GLASSES	SONY	TDG-500P	/

5. Indications for Use

This 3D Visualization System is intended to compose the imaging signals from video system center and convert them into 3D signals displayed on the monitor.

The indications for use statement of the subject device is similar to that of the video processor component of the predicate device; accordingly, the subject and predicate device have the same intended use.

6. Substantially Equivalent (SE) Comparison

Table 4. Substantially Equivalence Comparison

ITEM	Proposed Device	Predicate Device K123365
Product Code	HET, GCJ	HET, GCJ
Regulation Number	21 CFR 884.1720	21 CFR 884.1720
Class	II	II
Indications for Use	This 3D Visualization System is intended to compose the imaging signals from video system center and convert them into 3D signals displayed on the monitor.	This 3D processor is intended to be used with 3D videoscope and video system center for 3D observation.
Sterile	No	No
Single Use	No	No
Principle	Obtain the video signal from two image processor, mix them and convert into 3D image signal, and output it to monitor.	Obtain the video signal from two image processor, mix them and convert into 3D image signal, and output it to monitor.
Signal Output	SDI and HDMI	SDI
Signal Synchronization	Yes	Yes
2D/3D Image Switching	Yes	Yes
Image modes	Mode 1: single-lens endoscope, enhanced 3D effects Mode 2: single-lens endoscope, standard 3D effects Mode 3: dual-lens endoscope, enhanced 3D effects Mode 4: dual-lens endoscope, standard 3D effects	3D effect
Power Supply	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz

The proposed device can receive the HDMI signal and output the 3D HDMI signal to the monitor via HDMI cables, which is an additional function compared to predicate device. The HDMI function is optional for the proposed device. In addition, the proposed device has four image modes and the predicate device has one image mode.

The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as is substantially equivalent to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

The software of the proposed device was validated in accordance with the following guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff
- Off-The-Shelf Software Use in Medical Devices - Guidance for Industry, FDA Reviewers, and Compliance
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software - Guidance for Industry
- General Principles of Software Validation - Final Guidance for Industry and FDA Staff

For both 2D and 3D images, image quality performance tests were conducted to quantitatively compare the proposed device and predicate devices in terms of field of view and direction of view, depth of field, geometric distortion, noise and dynamic range, intensity uniformity, artifacts, and image frame frequency and system delay. For both 2D and 3D images, the four modes of the proposed device in both combinations were all tested in comparison to the predicate device. The image quality of the proposed device was equivalent to that of the predicate device.

8. Conclusion

The performance testing summarized above support a substantial equivalence determination. The performance testing demonstrate that the subject device is as safe and as effective as the legally marketed predicate device.