January 13, 2023

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

Re: K221252
Trade/Device Name: Scivita 4KINSIGHT ICG Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, IZI
Dated: December 12, 2022
Received: December 15, 2022

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,

Jianting Wang -S

Jianting Wang, Ph.D.
Acting 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)*
K221252

Device Name
Scivita 4KINSIGHT ICG Imaging System

Indications for Use *(Describe)*
The Scivita 4KINSIGHT ICG Imaging System consists of a 4KINSIGHT UHD Fluorescence Imaging System, a Near-Infrared LED Light Source, and a 4K UHD LAPAROSCOPE.
Upon intravenous administration of TRADENAME (ICG drug product), the Scivita 4KINSIGHT ICG Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography.
The Scivita 4KINSIGHT ICG Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The Scivita 4KINSIGHT ICG Imaging System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
Fluorescence imaging of biliary ducts with the Scivita 4KINSIGHT ICG Imaging System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.
Upon interstitial administration of TRADENAME (ICG drug product), the Scivita 4KINSIGHT ICG Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

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.

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: K221252

1. Date of Preparation: 12/12/2022

2. Sponsor Identification

Scivita Medical Technology Co., Ltd.
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3. Designated Submission Correspondent

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

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4. Identification of Subject device

Trade Name: Scivita 4KINSIGHT ICG imaging system
Common Name: 4K Fluorescence Imaging System

Regulatory Information
Classification Name: Gastroenterology-urology device
Classification: II;
Product Code: GCJ
Regulation Number: 21 CFR 876.1500
Review Panel: General & Plastic Surgery

Classification Name: Angiographic x-ray system
Classification: II;
Product Code: IZI
Regulation Number: 21 CFR 892.1600
Review Panel: Radiology

Indication for Use:
The Scivita 4KINSIGHT ICG Imaging System consists of a 4KINSIGHT UHD Fluorescence Imaging System, a Near-Infrared LED Light Source, and a 4K UHD LAPAROSCOPE.
Upon intravenous administration of TRADENAME (ICG drug product), the Scivita 4KINSIGHT ICG Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography.
The Scivita 4KINSIGHT ICG Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The Scivita 4KINSIGHT ICG Imaging System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
Fluorescence imaging of biliary ducts with the Scivita 4KINSIGHT ICG Imaging System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.
Upon interstitial administration of TRADENAME (ICG drug product), the Scivita 4KINSIGHT ICG Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Device Description:

The subject device, Scivita 4KINSIGHT ICG Imaging System is consisting of a 4KINSIGHT UHD Fluorescence Imaging System including a 4K Fluorescence Camera Control Unit and a 4K Fluorescence camera head, a Near-Infrared LED Light Source and a 4K UHD Laparoscope.

The subject device can be offered in multiple configuration based on different combination of component models and subcomponent models. Details refer to Table 1 System Configuration.

Table 1 System Configuration

System name	Component name and Model		Subcomponent/ Model
Scivita 4KINSIGHT ICG Imaging System	4KINSIGHT UHD Fluorescence Imaging System	4KIR01	4K Fluorescence Camera Control Unit/4KIR321
			4K Fluorescence Camera Head/4KIR320C
		4KIR07	4K Fluorescence Camera Control Unit/4KIR311
			4K Fluorescence Camera Head/4KIR320C
	Near-Infrared LED Light Source	LSIR330	/
	4K UHD Laparoscope	4K5500R, 4K5530R, 4K5545R, 4K1000R, 4K1030R, 4K1045 (these models have been cleared in **K203255**)	/
		4K5500L, 4K5530L, 4K5545L, 4K1000L, 4K1030L, 4K1045L, 4K5500LR, 4K5530LR, 4K5545LR, 4K1000LR, 4K1030LR, 4K1045LR	/

The component, 4KINSIGHT UHD Fluorescence Imaging System, is designed to be used with endoscopes, light source, monitors, light guide cables and other ancillary equipment for endoscopic diagnosis, treatment and observation. It is comprised of a 4K Fluorescence Camera Control Unit (model: 4KIR321, 4KIR311) and a 4K Fluorescence camera head (model 4KIR320C). The only difference between 4KIR321 and 4KIR3114K is: two HDMI output signal of 4KIR321 both are 4096×2160p; two HDMI output signal of 4KIR311 are respectively 4096×2160p and 1920×1080p.

The component, 4K UHD Laparoscope, is a rigid endoscope intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities. The subject device is also indicated for visualization of transanal and transvaginal applications.

The 4K UHD Laparoscope has 18 models which are available in two insertion portion widths (5.5 mm and 10 mm), four working lengths (290mm, 320mm, 424mm, 450mm) and three different directions of view (0 °, 30 °, 45 °). The 4K UHD Laparoscope is a reusable device that is cleaned and sterilized before first use and each use.

5. Identification of Predicate Device

510(k) Number: K182606
Product Name: PINPOINT Endoscopic Fluorescence Imaging System
Manufacturer: Novadaq Technologies ULC (now a part of Stryker)

6. Non-Clinical Test Conclusion

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

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance, including the US National Differences
- 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 performanc
- ISO 8600-1:2015 Endoscopes-Medical endoscopes and endotherapy devices-part 1: General requirements
- ISO 8600-5:2005 Endoscopes -Medical endoscopes and endotherapy devices--Part 5: Determination of optical resolution of rigid endoscopes with optics
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and System
- IEC 62471:2006 Photobiological safety of lamps and lamp systems

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological Characteristics

Table 2 General Comparison

ITEM	Subject Device	Predicate Device K182606	Remark
Product name	Scivita 4KINSIGHT ICG imaging system	PINPOINT Endoscopic Fluorescence Imaging System	/
Regulation No.	21 CFR 876.1500 21 CFR 892.1600	21 CFR 876.1500 21 CFR 892.1600	Same
Product Code	GCJ, IZI	GCJ, IZI	Same
Class	II	II	Same
Indication for Use	The Scivita 4KINSIGHT ICG Imaging System consists of a 4KINSIGHT UHD Fluorescence Imaging System, a Near-Infrared LED Light Source, and a 4K UHD LAPAROSCOPE. Upon intravenous administration of TRADENAME (ICG drug product), the Scivita 4KINSIGHT ICG Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography. The Scivita 4KINSIGHT ICG Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The Scivita 4KINSIGHT ICG Imaging System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood	Upon intravenous administration of TRADENAME (ICG drug product), the PINPOINT Endoscopic Fluorescence Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography. The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow	Same

	flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the Scivita 4KINSIGHT ICG Imaging System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Upon interstitial administration of TRADENAME (ICG drug product), the Scivita 4KINSIGHT ICG Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using nearinfrared imaging. Fluorescence imaging of biliary ducts with the PINPOINT System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Upon interstitial administration of TRADENAME (ICG drug product), the PINPOINT System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	
Main Configuration	4K UHD Laparoscope Near-Infrared LED Light Source 4K Fluorescence Camera Head 4K Fluorescence Camera Control Unit	Surgical laparoscope Illuminator (VPI) Camera head Endoscopic video processor	Different
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same
Prescription Use/OTC	Prescription Use	Prescription Use	Same

Different - Main Configuration

The naming of main configuration of the subject device is different from the predicate device, while they have the same main configuration. Therefore, the difference on naming of main configuration will not affect the safety and effectiveness of the subject device.

Table 3 Performance Comparison

ITEM		Subject Device	Predicate Device K182606	Remark
Endoscopes	Direction of View	0°, 30°, 45°	0°, 30°, 45°	Same
	Working Length	29cm (5.5mm, 0°, 30°, 45°)	300 mm	Different

		32cm (10mm, 0°, 30°, 45°)	302 mm 320 mm 323 mm 330 mm 420 mm	
Camera Head	Imager Type	CMOS	CMOS	Same
Camera Control Unit	Zoom	1x~ 2.5x	1x~ 2.5x	Same
	Digital Outputs	HDMI×2 SDI-1 BNC terminal×4 SDI-2 BNC terminal×1	HD-SDI, 3G-SDI, DVI	Different
Light Source	Light Source Type	White light LED and near-infrared light LED	Laser infrared light source	Different
Imaging Mechanism		The patient is injected with ICG imaging agent. Indocyanine green enters the blood through human intravenous injection and reaches various organs and tissues of the human body through human blood circulation. The ICG fluoresces when illuminated through the laparoscope with near-infrared excitation light from the near-infrared LED light source. The 4K fluorescence camera head captures the white light images reflected by human organs or tissues and the fluorescence images excited by indocyanine green. The light signals are collected and converted into electrical signals by the Complementary Metal Oxide Semiconductor (CMOS) inside the 4K fluorescence	The patient is injected with ICG imaging agent. Indocyanine green enters the blood through human intravenous injection and reaches various organs and tissues of the human body through human blood circulation. The ICG fluoresces when illuminated through the laparoscope with excitation light from the laser light source. The 4K fluorescence camera head captures the white light images reflected by human organs or tissues and the fluorescence images excited by indocyanine green. The light signals are collected and converted into electrical signals by the Complementary Metal Oxide Semiconductor (CMOS) inside the 4K fluorescence Camera Head, and then	Different

			Camera Head, and then transmitted to the 4K fluorescence camera control unit through the 4K fluorescence camera head cable. The 4K fluorescence camera control unit can process the image of the received electrical signal and transmit it to the 4K monitor through SDI and HDMI signal lines, and finally present the white light image and near infrared image on the display.	transmitted to the 4K fluorescence camera control unit through the 4K fluorescence camera head cable. The 4K fluorescence camera control unit can process the image of the received electrical signal and transmit it to the 4K monitor through SDI and HDMI signal lines, and finally present the white light image and near infrared image on the display.	
Contrast agent			Need	Need	Same
Contrast agent type			ICG	ICG	Same
Image Intensity	U_{corner}		52.5%	53.7%	Different
	U_{side}		80.9%	67.2%	
Depth of Field	Close view (3mm)		80.6 lp/mm	71.8 lp/mm	Different
	Distant view (250mm)		1.26 lp/mm	1.26 lp/mm	
Image resolution	Near DOF (3mm)	on-axis optical resolution	80.6 lp/mm	71.8 lp/mm	Different
		off-axis optical resolution	57.20 lp/mm	46.80 lp/mm	
	Working distance (40mm)	on-axis optical resolution	8.98 lp/mm	8.98 lp/mm	
		off-axis optical resolution	6.59 lp/mm	6.37 lp/mm	

	Far DOF (250mm)	on-axis optical resolution	1.26 lp/mm	1.26 lp/mm	
		off-axis optical resolution	1.16 lp/mm	1.12 lp/mm	
Light Source used for Fluorescent excitation			Near-Infrared LED Light Source	Laser source	Same
Wavelength			785nm	805 nm	Different

Different- Working Length

Although the working length of the subject device is not the same as that of the predicate device, the working length of the subject device is included in the scope of the predicate device. The surgeon will select the proper endoscope based on her/his experiences and clinical conditions. Thus, this difference does not affect substantially equivalence between the subject device and predicate device.

Different- Digital Outputs

Although the Digital Outputs of the subject device is different from that of the predicate device, the DVI does not support the 4K signal of 2160mm 108060p, while the subject device belongs to the 4K camera, so the picture quality is higher. Therefore, the performance should be better. Thus, this difference does not affect substantially equivalence between the subject device and predicate device.

Different- Light Source

The Light Source Type of the subject device is not the same as that of the predicate device. The subject device uses the LED infrared light source and the predicate device uses laser infrared light. LED is a low-energy light, which is safer than the laser infrared light. Therefore, the subject device is better than the predicate device on Light Source Type.

Different- Imaging Mechanism and Wavelength

The Light Source used for Fluorescent excitation for the subject device is LED infrared light source, and for the predicate device it is the Laser infrared light source. Because the light source type is different, the output wavelength is similar but not the same. The absorption spectrum of ICG in blood is 650nm-850nm, and in one Study, it shows that the infrared light near 765nm produces the most fluorescence. Therefore, we believe this difference on wavelength does not affect substantially equivalence between the subject device and predicate device, and the subject device and predicate device has the same imaging mechanism.

Different- Image Intensity

The intensity uniformity of subject device is almost same with predicate device in U_{corner}, the intensity uniformity of U_{side} of subject device is better than predicate device, which demonstrates that the intensity uniformity performance of subject device is better than predicate device. Thus, this difference does not affect substantially equivalence between the subject device and predicate device.

Different- Depth of Field

The resolution of subject device and predicate device is almost the same in the testing distance scope (3mm-250mm), although the asserted depth of field of predicate device is 25mm-100mm, but the resolution of subject device and predicate device all meet the depth of field criteria (3mm-250mm), which demonstrates that subject device and predicate device almost have the same depth of field performance. Thus, this difference does not affect substantially equivalence between the subject device and predicate device.

Different- Image resolution

Base on the compare analytical data, the on-axis optical resolution and the average off-axis optical resolution of subject device is almost the same with predicate device in the near DOF (3mm), working distance (40mm), far DOF (250mm) which demonstrates that the resolution performance of subject device is almost the same with predicate device. Thus, this difference does not affect substantially equivalence between the subject device and predicate device.

9. Substantially Equivalent (SE) Conclusion

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