May 26, 2026

Zhejiang Healnoc Technology Co., Ltd.
% Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Rm.1308, Baohua International Plaza, W. Guangzhong Rd. 555
Jingan District
Shanghai,
China

Re: K260318
Trade/Device Name: 4K NIR/ICG Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, IZI
Dated: January 21, 2026
Received: January 30, 2026

Dear Kyra Kang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSICA CARR -S

Jessica Carr, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260318

Device Name
4K NIR/ICG Imaging System

Indications for Use *(Describe)*

Endoscopic Camera System:

Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Camera System is intended to provide real-time endoscopic visible and near-infrared fluorescence visualization. The 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, using near-infrared imaging.

Upon interstitial administration and use of an ICG consistent with its approved label, the Endoscopic Camera System is intended to be used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Endoscopic Cold Light Source:

The Endoscopic Cold Light Source in combination with the camera head and camera control unit is used for visualizing endoscopic procedures.

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 – K260318

I. Submitter

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Preparation date: May 26th, 2026

Submission Correspondent
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Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	4K NIR/ICG Imaging System
Common name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Primary product code:	GCJ
Secondary product code:	IZI
Review Panel:	Radiology

III. Predicate Devices

510(k) Number:	K182606
Trade name:	PINPOINT Endoscopic Fluorescence Imaging System
Common name:	Endoscope and accessories
Classification:	Class II
Product Code:	GCJ, IZI
Manufacturer	Novadaq Technologies ULC (now a part of Stryker)

IV. Device description

The 4K NIR/ICG Imaging System consists of the Endoscopic Camera System and the Endoscopic Cold Light Source.

Endoscopic Camera System is composed of a camera control unit and a camera head. The Endoscopic Camera System is for use with endoscopic cold light source and endoscope and is used for visualizing and documenting endoscopic procedures.

The Endoscopic Cold Light Source consists of a light source and a power cord. The light source features LED lamp assembly output white light and LD semiconductor laser output near-infrared laser, and contains the fiber optic light cable. The light source consists of a panel, a touchscreen, a control circuit, a brightness adjustment circuit, a housing, a fan assembly， an LED lamp assembly, an LD lamp assembly, a heat sink and a switching power supply. The Endoscopic Cold Light Source in combination with the camera head and camera control unit is used for visualizing endoscopic procedures.

V. Indications for use

Endoscopic Camera System:

Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Camera System is intended to provide real-time endoscopic visible and near-infrared fluorescence visualization. The 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, using near-infrared imaging.

Upon interstitial administration and use of an ICG consistent with its approved label, the Endoscopic Camera System is intended to be used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Endoscopic Cold Light Source:

The Endoscopic Cold Light Source in combination with the camera head and camera control unit is used for visualizing endoscopic procedures.

VI. Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate devices are listed in the table below.

General Comparison

Characteristics	**Proposed device**	**Predicate device (K182606)**	**Discussion**
Device Name	4K NIR/ICG Imaging System	PINPOINT Endoscopic Fluorescence Imaging System	/
Product Code	GCJ, IZI	GCJ, IZI	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Classification	Class II	Class II	Same
Type of use	Prescription Use	Prescription Use	Same
Intended use & Indications for Use	Endoscopic Camera System: Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Camera System is intended to provide real-time endoscopic visible and near-infrared fluorescence visualization. The 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, using near-infrared imaging. Upon interstitial administration and use of an	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	Same

	ICG consistent with its approved label, the Endoscopic Camera System is intended to be used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. Endoscopic Cold Light Source: The Endoscopic Cold Light Source in combination with the camera head and camera control unit is used for visualizing endoscopic procedures.	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 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.	
Applicable	Physicians	Physicians	Same

user			
Environment of use	Healthcare facility /hospital	Healthcare facility /hospital	Same
Single use / Reusable	Reusable	Reusable	Same
Sterile /non sterile	Marketed as non-sterile	Marketed as non-sterile	Same
Device System components	Endoscopic Camera System is composed of a camera control unit and a camera head. Endoscopic Cold Light Source consists of a cold light source and a power cord.	-Endoscopic video processor/illuminator(VPI) -Laparoscope -Camera head -Light guide cable	Analysis 1
Video output signals	SDI (3G-SDI,12G-SDI) DVI HDMI(HDMI 1.4,HDMI 2.0)	HD-SDI, 3G-SDI, DVI	Analysis 2
Video output resolution	4096×2160P, 3840×2160P, 1920×1080P	1920×1080	Analysis 3
Voltage	100V-240V～	100-240V~	Same
Frequency	50/60 Hz	50/60 Hz	Same
Power consumption	100VA	300VA	Analysis 4
Image sensors	2 CMOS sensors	CMOS HD sensor assembly	Analysis 5
Aspect ratio	16:9	16:9	Same
Light sources	White LED and near-infrared laser	-Visible (VIS): Light-emitting diode Array -Near infrared (NIR): NIR laser diode	Same

Wavelength(NIR)	785±5nm	805±4nm	Analysis 6
Power density(NIR)	27.43 mW/cm^2	29.51 mW/cm^2	Analysis 7
Working distance	50mm	50mm	Same
Light guide cable	Transmission spectrum: Visible + NIR	Transmission spectrum: Visible + NIR	Same
	Sterilization: Autoclave	Sterilization: Autoclave	Same
Imaging agent	Indocyanine Green (ICG)	Indocyanine Green (ICG)	Same
Type of protection against electric shock (as per IEC 60601-1)	Class I	Class I	Same
Degree of protection against electric shocks (as per IEC 60601-1)	CF-type	CF-type	Same
Laser classification (as per IEC 60825-1)	Class 3R	Class 3R	Same
Radio	Group 1, Class A	Group 1, Class A	Same

frequency emissions (as per CISPR 11)			

Analysis 1 Device system components

The Proposed Device does not include a laparoscope as a provided component. However, it is designed and intended to be used with laparoscopes that are legally marketed in the United States. The compatibility with commercially available laparoscopes ensures that the system functions identically to the Predicate Device in terms of imaging capability, light delivery, and clinical application. No additional safety or effectiveness risks are introduced, as the laparoscope is a standalone, cleared device used in accordance with its labeled instructions.

Analysis 2 Video Output Signals

The Proposed Device provides additional video output formats (12G-SDI and HDMI 1.4/2.0) compared to the Predicate Device. These formats are backward compatible with existing HD-SDI/3G-SDI and DVI interfaces commonly used in surgical environments. The inclusion of HDMI 1.4/2.0 and 12G-SDI supports higher resolution (4K) and broader monitor compatibility, which are enhancements that do not alter the fundamental video output function or introduce new risks. All output signals comply with recognized industry standards and maintain electrical and signal compatibility with standard medical displays.

Analysis 3 Video output resolution

These higher resolutions provide enhanced image clarity and detail, which are beneficial for surgical visualization but do not alter the fundamental imaging function or introduce new risks. The device maintains backward compatibility with 1080P output, ensuring it can be used with existing monitor systems. The increased resolution is achieved through advancements in imaging sensor and processing technology, which are well-established and do not affect safety or performance.

Analysis 4 Power Consumption

Lower power consumption reduces thermal output, enhances device reliability, and decreases operational costs, without compromising performance or safety. The electrical safety and compliance with relevant standards are maintained, and the device continues to operate within typical hospital power supply specifications.

Analysis 5 Image sensors

This dual-sensor configuration is a technological advancement that enhances imaging capability without altering the fundamental imaging mechanism or introducing new risks. Both systems comply with relevant imaging performance and safety standards.

Analysis 6 Wavelength(NIR)
The principle of ICG fluorescence imaging is that indocyanine green (ICG) absorbs NIR light in the wavelength range of 750 – 810 nm and subsequently emits fluorescence. Both the wavelength(NIR) of subject device and predicate device are in the range of 750 – 810 nm, and the subject device has been tested according to IEC 60825-1, so the difference will not affect the safety and effectiveness.

Analysis 7 Power density(NIR)
The power density(NIR) of subject device is lower than that of predicate device, the lower power density(NIR), the lower risk of thermal injury, and the power density(NIR) of subject device has been verified, and the subject device has been tested according to IEC 60825-1, so the difference will not affect the safety and effectiveness.

VII. Non-Clinical Testing
The device described in this summary, were tested and demonstrated to be in conformance with the following standards:

Performance testing :
A comparison testing with the predicate device was conducted to demonstrate substantial equivalence. Specifically, tests were performed on the following items:
Noise and Dynamic Range Test of Near-infrared Fluorescence Imaging;
Penetration depth Test of Near-infrared Fluorescence Imaging;
Sensitivity and Signal linearity Test of Near-infrared Fluorescence Imaging;
Signal Uniformity Test Report of Near-infrared Fluorescence Imaging;
Excitation Light Crosstalk of Near-infrared Fluorescence Imaging Test;
Noise and Dynamic Range Test;
Color Reproduction Test;
Intensity Uniformity Test;
Opto-electronic conversion function(OECFs) Test ;
Depth of Field Test;
Relative Distortion Test;
Resolution Test
Image Frame Frequency and System Delay Test

Software
Guidance for Industry and Food and Drug Administration Staff-Content of Premarket Submissions for Device Software Functions

Cybersecurity
Guidance for Industry and Food and Drug Administration Staff-Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Electrical Safety and EMC
IEC 60601-1-2
IEC TS 60601-4-2
IEC 60601-1
IEC 60601-2-18
IEC 60825-1
IEC 62471

VIII. Clinical Testing
No clinical study is included in this submission.

IX. Conclusion
The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.