August 7, 2024
Guangdong OptoMedic Technologies, Inc.
Minghua Wu
Regulatory Affairs Engineer
Suite 503, Building A, Golden Valley Intellicreation
Community, No. 2 Yonganbei Street
Foshan, 528200
China

Re: K241530
Trade/Device Name: Stellar Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 29, 2024
Received: May 30, 2024

Dear Minghua Wu:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

for Yan Fu -S Digitally signed by Yan Fu -S Date: 2024.08.07 11:03:48 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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)*
K241530

Device Name
Stellar Imaging System

Indications for Use *(Describe)*
UseStellar Imaging System is intended to provide real-time visible and near-infrared imaging in minimally invasive procedures.
Upon intravenous administration and use of an ICG agent consistent with its approved label, Stellar Imaging System is used to perform fluorescence imaging and visualization of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts.
Upon interstitial administration and use of an ICG agent consistent with its approved label, the Stellar 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.**

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.***

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# 510(k) Summary K241530

## Prepared in accordance with the requirements of 21 CFR Part 807.92

The assigned 510(k) Number: K241530

Date Prepared: July 26, 2024

### I. General Information

| | |
|---|---|
| 510(k) Submitter/Owner: | Guangdong OptoMedic Technologies, Inc.<br>Suite 503, Building A, Golden Valley Intellicreation Community, No. 2 Yonganbei Street, Daxu, Guicheng, Nanhai, Foshan, Guangdong, 528200, P.R. China<br>Establishment Registration Number: 3029968414 |
| Primary Contact Person: | Minghua Wu<br>Regulatory Affairs Engineer<br>Tel: +86 (757) 8670 2920<br>Email: wuminghua@optomedic.com |
| Secondary Contact Person: | Weijuan Guo<br>Regulatory Affairs Engineer<br>Tel: +86 (757) 8670 2920<br>Email: guoweijuan@optomedic.com |

### II. Device Identification

| | |
|---|---|
| Device Trade Name: | Stellar Imaging System |
| Common or Usual Name: | Stellar Imaging System |
| Model: | Stellar Image Processing Unit:SI10E<br>Stellar Camera Head: SC10E<br>Stellar Fluorescence Camera Head: SC20E<br>Stellar$^{3D}$ 3D Camera Head: SC10D<br>Stellar$^{3D}$ 3D Fluorescence Camera Head: SC20D<br>Stellar Exoscope: 31103FA<br>Stellar Light Source: SL10<br>Stellar Light Source: SL20<br>OptoMedic Laparoscope: 21033FA, 21033FC, 21033WA, 21033WC, 20533FA, 20533FC, 20533WA, 20533WC(K231003)<br>Stellar$^{3D}$ Laparoscope 21033SA,21033SC |

| | |
|---|---|
| Regulation Name: | Endoscope and accessories |
| Regulation Number: | 21 CFR § 876.1500 |
| Regulatory Class: | Class II |
| Product Code: | GCJ |

## III. Predicate Device

Table 1 Predicate device and reference device

| **Item** | Predicate device | Reference device |
|---|---|---|
| **510(k) Number:** | K221861 | K101810 |
| **Product Name:** | FloNavi Endoscopic Fluorescence Imaging System | 3DHD Video Camera System |

## IV. Device Description

Stellar Imaging System comprises Image Processing Unit, Light Source, Camera Head, Laparoscope, Exoscope and relevant accessories.

During surgical procedures, Stellar Imaging System is used to provide real-time visible and fluorescence imaging similar to that provided by conventional imaging system used in endoscopic surgery and innovative 3D visible and fluorescence imaging in endoscopic surgery. Besides, Stellar Imaging System is also used to provide real-time fluorescence confirmation in open field.

The Stellar Imaging System including the laparoscope and the exoscope is designed to work with an approved infrared dye (Indocyanine green (ICG). ICG may be excited at excitation at either 785 or 805 nm. The System provides excitation light to the surgical field to excite the dye molecules and captures emission from the dye using a camera head. Fluorescence imaging with ICG permits the system to visualize blood flow and related tissue circulation, of lymphatic flow, etc.

The System allows the capture of normal (white) light image in parallel with the fluorescence image and displays both to the surgeon to provide a view of the anatomy. In addition, the System permits recording surgical procedures, storing them on removable storage devices, and replaying the procedures.

## V. Indications for Use

Stellar Imaging System is intended to provide real-time visible and near-infrared imaging in minimally invasive procedures.

Upon intravenous administration and use of an ICG agent consistent with its approved label, Stellar Imaging System is used to perform fluorescence imaging and visualization of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts.

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

## VI. Comparison of Technological Characteristics with The Predicate Device

Table 2 General Comparison with predicate device

| **Comparison items** | **Subject Device** | **Predicate Device (**K221861**)** |
|---|---|---|
| Regulation Number | 21 CFR § 876.1500 | 21 CFR § 876.1500 |
| Product Code | GCJ | GCJ |
| Device class | Class II | Class II |
| Type of use | Prescription Use | Prescription Use |
| Intended use & Indication for use | Stellar Imaging System is intended to provide real-time visible and near-infrared imaging in minimally invasive procedures.<br><br>Upon intravenous administration and use of an ICG agent consistent with its approved label, Stellar Imaging System is used to perform fluorescence imaging visualization of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts.<br>Upon interstitial administration and use of an ICG agent consistent with its approved label, the Stellar Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. | Upon intravenous administration and use of an ICG consistent with its approved label, the FloNavi Endoscopic Fluorescence Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. During minimally invasive surgery, the FloNavi Endoscopic Fluorescence Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic 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.<br>Upon interstitial administration and use of an ICG consistent with its approved label, the FloNavi Endoscopic Fluorescence Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. |
| Applicable user | Physicians | Physicians |
| Environment of use | Healthcare facility/hospital | Healthcare facility/hospital |
| Single use /Reusable | Reusable | Reusable |
| Sterile /nonsterile | Marketed as non-sterile | Marketed as non-sterile |

| | | | |
|---|---|---|---|
| Device System components | | - Image Processing Unit<br>- Camera Head<br>- Light Source<br>-Laparoscope<br>- Light Guide Cable | - Image Processing Unit<br>- Camera Head<br>- Light Source<br>-Laparoscope<br>- Light Guide Cable |
| **Image processing Unit (SI10E)** | Video output signals | DVI, HDMI, 4×3G-SDI, 12G-SDI | OPTO-CAM214K：DVI, HDMI, 4×3G-SDI, 12G-SDI<br>OPTO-CAM 2100：SDI, DVI, CVBS, SVIDEO |
| | Video output resolution | 2D: 1920×1080p / UHD(3840x2160)/ 4K(4096x2160); | OPTO-CAM214K：4096×2160p; 3840×2160p; 1920×1080p<br>OPTO-CAM2100: 1920×1080p; 720×576i |
| | Aspect ratio | 16:9 | 16:9 |
| | Electrical Power | 110-240V~, 50/60 Hz, 150VA | 110-240V~, 50/60 Hz, 150VA |
| | Type of protection against electric shock | Class I (as per IEC 60601-1) | Class I (as per IEC 60601-1) |
| **Camera Head (SC10E, SC20E)** | Sensor | 4K CMOS | 4K CMOS |
| | Aspect ratio: | 16:9 | 16:9 |
| | Ingress of water | IPX7 | IPX7 |
| | Sterilization | Low temperature plasma sterilization | Glutaraldehyde |
| | Imaging mode | SC10E: Support 2D white light imaging.<br>SC10D: Support 3D white light imaging.<br>SC20E: Support 2D white light imaging and fluorescence imaging.<br>SC20D: Support 3D white light imaging and fluorescence imaging. | Support 2D white light imaging and fluorescence imaging. |
| **Light source** | Light Source | Visible (VIS): Light-emitting diode array | Visible (VIS): Light emitting diode array |

| | | | |
|---|---|---|---|
| (SL10, SL20) | | Near infrared (NIR): NIR laser diode | Near infrared (NIR): NIR laser diode |
| | Electrical Power | 110-240V~, 50/60 Hz, 200VA | 110-240V~, 50/60 Hz, 200VA |
| | Type of protection against electric shock | Class I (as per IEC 60601-1) | Class I (as per IEC 60601-1) |
| **Light source** (SL20) | NIR Wavelength: | 805 nm±10 nm | 805 nm±10 nm |
| | Pulse Pattern: | CW laser | CW laser |
| | Embedded laser source | Class 4, invisible | Class 4, invisible |
| | Laser classification | Class 3R (as per IEC 60825-1) | Class 3R (as per IEC 60825-1) |
| **Light source** (SL10) | LED classification | RISK GROUP 2<br>400 nm to 780 nm Retinal blue light or thermal hazard (as per IEC/TR 62471-2) | RISK GROUP 2<br>400 nm to 780 nm Retinal blue light or thermal hazard (as per IEC/TR 62471-2) |
| Light guide cable | Transmission spectrum | Visible + NIR | Visible + NIR |
| | Sterilization | Autoclave | Autoclave |
| | Degree of protection against electric shocks | CF-type (as per IEC 60601-1) | CF-type (as per IEC 60601-1) |

The differences technological characteristics do not raise different questions of safety and effectiveness.

## VII. Performance data

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

- ANSI/AAMI ES 60601-1: 2005+A2 (R2012) +A1 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular

requirements for the basic safety and essential performance of endoscopic equipment
- AAMI ST98 Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices.
- AAMI TIR 12:2020 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- IEC 60825-1 Edition 2.0 2007-03 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems

Performance comparison testing are also conducted on the subject device and predicate/reference device, demonstrate that the proposed system performs according to specifications and functions as intended.

**VIII. Conclusions**

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