



October 29, 2025

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

Re: K252697

Trade/Device Name: 3D Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 10, 2025
Received: September 11, 2025

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.

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,

Colin K.
Chen -S

Digitally signed by Colin K. Chen -
S
Date: 2025.10.29 21:29:38 -04'00'

Colin Kejing Chen
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252697

?

Please provide the device trade name(s).

?

Stellar Imaging System

Please provide your Indications for Use below.

?

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 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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Guangdong OptoMedic Technologies, Inc.
Applicant Address	Suite 503, Building A, Golden Valley Intellicreation Community, No. 2 Yonganbei Street, Daxu, Guicheng, Nanhai, 528200, Foshan, Guangdong, P.R. China Foshan 528200 China
Applicant Contact Telephone	0757-8670-2920
Applicant Contact	Ms. Minghua Wu
Applicant Contact Email	wuminghua@optomedic.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Stellar Imaging System
Common Name	Endoscope and accessories
Classification Name	laparoscope, general & plastic surgery
Regulation Number	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241530	Stellar Imaging System	GCJ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Stellar Imaging System comprises Image Processing Unit, Light Source, Camera Head, Laparoscope and relevant accessories. During surgical procedures, Stellar Imaging System is used to provide real-time 3D visible and fluorescence imaging in endoscopic surgery.

The Stellar Imaging System including the laparoscope 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.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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 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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The differences between changed 21033SA,21033SC, new models 21050SA,21050SC and cleared 21033SA,21033SC are:

1. Field of view: The field of view of changed 21033SA,21033SC, new models 21050SA,21050SC is 80°, while cleared 21033SA,21033SC is 70°.
2. Maximum insertion portion width (mm): The maximum insertion portion width of changed 21033SA,21033SC, new models 21050SA,21050SC is 10.3, while cleared 21033SA,21033SC is 10.1.
3. Working length (mm): The working length of changed 21033SA,21033SC is 300, new models 21050SA,21050SC is 490, while cleared 21033SA,21033SC is 315.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

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