February 19, 2025

Optosurgical LLC
Yoseph Kim
Chief Executive Officer and R&D Administrator
6751 Columbia Gateway Dr, Suite 300
Office 313
Columbia, Maryland 21046

Re: K243591
Trade/Device Name: OPTOVISION Endoscopic Light Source Unit
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: October 31, 2024
Received: November 20, 2024

Dear Yoseph Kim:

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.19 16:05:57 -05'00'

Tanisha Hithe
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.

Submission Number *(if known)*

K243591

Device Name

OPTOVISION Endoscopic Light Source Unit

Indications for Use *(Describe)*

Upon intravenous administration of ICG(Indocyanine green for injection) consistent with its approved label, the OPTOVISION provides real-time endoscopic visible and near-infrared fluorescence imaging. The OPTOVISION enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 and common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the OPTOVISION 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 and use of ICG consistent with its approved label, the OPTOVISION 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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

I. 510(k) Submitter

Applicant: OPTOSURGICAL LLC.
6751 Columbia Gateway Drive Suite 300, Office 313, Columbia, MD 21046

Contact Person: Yoseph Kim / Chief Executive Officer and R&D Administrator
Phone: +1-203-675-7089
Email: yoseph.kim@optosurgical.com
Date Prepared: February 17, 2025

II. Subject Device

- Name of Device: OPTOVISION Endoscopic Light Source Unit
- Common or Usual Name: Light Source, Illuminator
- Classification Name: Confocal Optical Imaging
- Regulation Name: Endoscope and accessories (21 CFR 876.1500)
- Regulatory Class: II
- Product Code: OWN

III. Predicate Device

- Proprietary Name: AIM Light Source and SafeLight™ Cable
- 510(k) Number: K192292
- Common Name: Light Source, Illuminator
- Classification Name: Confocal Optical Imaging & Fiberoptic light ureteral catheter & Light Source, Fiberoptic, Routine
- Regulation Name: Endoscope and accessories & Fiberoptic light ureteral catheter
- Regulation: 21 CFR 876.1500 & 21 CFR 876.4020 & 21 CFR 876.4020
- Product Code: OWN, FSC, FCW

IV. Description

OPTOVISION is an endoscopic light source that enables real-time endoscopic visible and near-infrared fluorescence imaging during minimally invasive surgical procedures. Near-infrared illumination is used for fluorescence imaging using indocyanine green (ICG). This device is largely composed of a power circuit, a control circuit, and a lighting lamp (light source). A power circuit provides power to the lighting lamp and cuts off the power in an emergency, a control circuit controls the light output (intensity)/other settings of light rays, and a light source unit irradiates light directly to the Light Guide Cable (K111342) for observation of the affected area. With the configuration above, the power input from the initial power source is transmitted to the light source unit and the main body, and rays of white light and near-infrared light are directly irradiated through the Light Guide Cable to the affected area for observation. This device is designed for use in the following applications: standard endoscopic visible-light imaging and near-infrared fluorescence imaging.

V. Indications for Use

Upon intravenous administration of ICG (Indocyanine green for injection) consistent with its

approved label, the OPTOVISION provides real-time endoscopic visible and near-infrared fluorescence imaging. The OPTOVISION enables surgeons to perform minimally invasive surgery using standard endoscope visual 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 and common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the OPTOVISION 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 and use of ICG consistent with its approved label, the OPTOVISION 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

The subject device is substantially equivalent to AIM Light Source and SafeLight™ Cable (K192292). The subject device has the same indications for use and technological characteristics as the predicate device. It also has identical specifications as the predicate device in almost all parameters. The imaging mode is a minor difference between the subject and predicate device [AIM Light Source and SafeLight™ Cable (K192292)]. However, these differences do not raise a question in substantial equivalence.

	Subject device	Predicate Device	Comment
Manufacturer	OPTOSURGICAL LLC.	Stryker Endoscopy	-
Common or Usual Name	Light Source, Illuminator	Light Source, Illuminator	
Classification Name	Confocal Optical Imaging	Confocal Optical Imaging	-
Brand Name	OPTOVISION Endoscopic Light Source Unit	AIM Light Source and SafeLight™ Cable	-
Model Name	OPSFI2241	L10 & L11	-
Regulatory Class	II	II	-
CFR Regulation	21 CFR 876.1500	21 CFR 876.1500	-
Product Code	OWN	OWN, FSC, FCW	-
510(k) Number	K243591	K192292	-
Intended Use	Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	**Same as predicate**
Indications for Use	NOTE 1	NOTE 2	**Similar to predicate** Although the predicate device includes the additional intended use of transilluminating the ureter, the subject device shares the same intended use as the predicate device in using ICG fluorescence imaging for real-time endoscopic visible and near-infrared fluorescence imaging of vessels, blood flow, related tissue perfusion, and bile ducts. This difference does not raise different questions of safety and effectiveness.

	Subject device	Predicate Device	Comment
Principles of Operation	An electronic driver controls Red/Green/Blue LEDs and a near-infrared laser diode which are combined through dichroic mirrors and projected onto an output light collimator. A fiber output bundle can be inserted into the light source to couple light to the distal end and into an endoscope.	An electronic driver controls Red/Green/Blue LEDs and a near-infrared laser diode which are combined through dichroic mirrors and projected onto an output light collimator. A fiber output bundle can be inserted into the light source to couple light to the distal end and into an endoscope.	**Same as predicate**
Components	Light Source Unit Light Guide Cable	Light Source and SafeLight Cable Camera System Laparoscopes IRIS Ureteral Kit Imaging Agent	**Similar to predicate** The OPTOVISION consists of a Light Source Unit and offers a light guide cable (K111342). This light guide cable is universally manufactured by a third party, and thus follows the reprocessing procedures established by the respective manufacturer. This difference does not raise different questions of safety and effectiveness, as discussed above.
Safety Standards	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 62471	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1	**Similar to predicate** Safety related to OPTOVISION's light source has been evaluated and demonstrated in compliance with IEC 62471. This difference does not raise different questions of safety and effectiveness, as discussed above.
Light Source / Laser	RGB LEDs Infrared Laser	RGB LEDs Infrared Laser	**Same as predicate**
Infrared Wavelengths	808nm (used for NIR fluorescence)	806nm (used for NIR fluorescence) 830nm (used for NIR transillumination)	**Similar to predicate** Both the 808nm and 806nm wavelengths are used for NIR fluorescence imaging with ICG, and the difference between these wavelengths is substantially the same in terms of the functionality provided by the subject device and the predicate device. This difference does not raise different questions of safety and effectiveness, as discussed above.

		Subject device	Predicate Device	Comment
Imaging Mode	**White Light**	Manual Autolight	Manual Autolight	**Same as predicate**
	NIR Fluorescence	NIR VIS FUSION	ENV Contrast Overlay	**Similar to predicate** Both the subject device and predicate device passed the bench test criteria according to the recognized consensus standard EN/IEC 60601-1-2. The "NIR" mode of the subject device is functionally equivalent to the "Contrast" mode of the predicate device, and the "FUSION" mode of the subject device is functionally equivalent to the "Overlay" mode of the predicate device. While the subject device does not support the "ENV" mode, this does not result in any technical differences in the primary function of providing NIR fluorescence imaging using ICG between the two devices. This difference does not raise different questions of safety and effectiveness, as discussed above.
Light Guide Cable	**Single-Use/ Reusable**	Reusable	Reusable	**Same as predicate**
Type of Use		Prescription Use	Prescription Use	**Same as predicate**

NOTE 1: Upon intravenous administration of ICG (Indocyanine green for injection) consistent with its approved label, the OPTOVISION provides real-time endoscopic visible and near-infrared fluorescence imaging. The OPTOVISION enables surgeons to perform minimally invasive surgery using standard endoscope visual 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 and common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the OPTOVISION 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 and use of ICG consistent with its approved label, the OPTOVISION is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

NOTE 2: Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the AIM Light Source and SafeLight™ Cable is used with SPY AGENT GREEN to provide real-time endoscopic visible and near-infrared fluorescence imaging. The AIM Light Source and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 and common hepatic duct), using near-infrared imaging.

Fluorescence imaging of biliary ducts with the AIM Light Source and SafeLight Cable is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

Upon interstitial administration of SPY AGENT GREEN (ICG drug product), the AIM Light Source and SafeLight Cable is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic

vessels and lymph nodes.

The AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Testing	Method	Result
Electrical Safety	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] IEC 60601-2-18: Edition 3.0 2009-08 IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	PASS
Electromagnetic Compatibility (EMC) test	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	PASS
Usability	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	PASS
Photobiological Safety	IEC 62471 First edition 2006-07	PASS
Software Validation & Verification	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	PASS
Performance - Bench	In accordance with device input specifications	PASS

All conducted tests demonstrated compliance with applicable standards, and no safety concerns were identified.

VIII. Conclusions

Based on the information provided in this premarket notification, OPTOVISION Endoscopic Light Source Unit is substantially equivalent to the predicate device as described herein in safety and effectiveness. The OPTOVISION Endoscopic Light Source Unit has the same intended use and similar indications for use as its predicate device, AIM Light Source and SafeLight™ Cable (K192292). Further, the OPTOVISION Endoscopic Light Source Unit has very similar technological characteristics and principles of operation as its predicate device, AIM Light Source and SafeLight™ Cable (K192292). The minor technological differences between the subject and the predicate devices do not raise different questions of safety or effectiveness. Performance testing of the device has demonstrated that the device performs as intended and thus, is substantially equivalent.