July 17, 2023

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

Re: K230407
Trade/Device Name: FloNavi Open Field Fluorescence Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN, IZI, GCJ
Dated: July 15, 2023
Received: July 17, 2023

Dear Alice Lau:

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,

Jessica Carr -S

Jessica Carr, PhD
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)*
K230407

Device Name
FloNavi Open Field Fluorescence Imaging System

Indications for Use *(Describe)*
Upon intravenous administration and use of an ICG consistent with its approved labeling, the FloNavi Open Field Fluorescence Imaging System is used to perform intraoperative fluorescence angiography.

The FloNavi Open Field Fluorescence Imaging System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.

Upon interstitial administration and use of an ICG consistent with its approved labeling, the FloNavi Open Field Fluorescence 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.

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K230407 510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: June 9, 2023

I. General Information

510(k) Submitter/Owner:	Guangdong OptoMedic Technologies, Inc. Suite 503, Building A, Golden Valley Intellicreation Community, No. 2 Yonganbei Street, Daxu, Guicheng, Nanhai, Foshan, Guangdong, 528200, P.R. China Establishment Registration Number: Not yet registered
Primary Contact Person:	Alice Lau Regulatory Affairs Engineer Tel: +86 (757) 8670 2920 Email: liuli@optomedic.com

II. Device Identification

Device Trade Name:	FloNavi Open Field Fluorescence Imaging System
Model:	HD system: Image Processing Unit (OPTO-CAM2100), Imaging Head (OPTO-CHD3100H; OPTO-CHD3100E) 4K system: Image Processing Unit (OPTO-CAM214K), Imaging Head (OPTO-CHD314KE)
Common or Usual Name:	Fluorescence Angiographic System
Regulation Name:	Endoscopes and accessories
Regulation Number:	21 CFR § 876.1500
Regulatory Class:	Class II
Product Code:	OWN, IZI, GCJ

III. Predicate Device

510(k) Number: K200737

Product Name: SPY Portable Handheld Imaging (SPY-PHI) System

The predicate device has not been subject to a design-related recall.

IV. Device Description

The FloNavi Open Field Fluorescence Imaging System is an imaging system used in hospitals for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue transfer circulation for use in imaging during various surgical procedures.

The FloNavi Open Field Fluorescence Imaging System has two system models: HD system and 4K system. Each system consists of the following main components: Imaging Head, Image Processing Unit, power supply cord and video cables.

The Imaging Head may be either handheld or attached to a mechanical arm and provides illumination of the regions of a patient's body to be observed with near infrared light to excite ICG fluorescence. Alternatively, the Imaging Head provides white light illumination of the regions of a patient's body to be observed for color imaging. The cameras in the Imaging Head capture the fluorescent image under near infrared illumination or a color image under white light illumination. The Image Processing Unit receives the video signal from the Imaging Head and processes and outputs the video image to a medical grade video monitor and/or video recorder. Adjustments to the operation of the FloNavi Open Field Fluorescence Imaging System are possible through switches at either the Imaging Head or the Image Processing Unit.

The FloNavi Open Field Fluorescence Imaging System is a reusable device and provided non-sterile. Its components should be cleaned and low-level disinfected prior to the first use and after every subsequent use.

V. Indications for Use

Upon intravenous administration and use of an ICG consistent with its approved labeling, the FloNavi Open Field Fluorescence Imaging System is used to perform intraoperative fluorescence angiography.

The FloNavi Open Field Fluorescence Imaging System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.

Upon interstitial administration and use of an ICG consistent with its approved labeling, the FloNavi Open Field Fluorescence 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 1 General Comparison

Description	Subject Device	Predicate device
	FloNavi Open Field Fluorescence Imaging System	**SPY Portable Handheld Imaging (SPY-PHI) System**
510(k) Holder / Manufacturer	Guangdong OptoMedic Technologies, Inc.	Novadaq Technologies ULC. (now a part of Stryker)
Submission Reference	K230407	K200737
Combination Product	No	No
Product Code	OWN, IZI, GCJ	OWN, IZI, GCJ
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Device Classification Name	Confocal Optical Imaging	Confocal Optical Imaging
Indications for Use	Upon intravenous administration and use of an ICG consistent with its approved labeling, the FloNavi Open Field Fluorescence Imaging System is used to perform intraoperative fluorescence angiography. The FloNavi Open Field Fluorescence Imaging System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures. Upon interstitial administration and use of an ICG consistent with its approved labeling, the FloNavi Open Field Fluorescence Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	Upon intravenous administration of SPY AGENT™ GREEN (indocyanine green for injection, USP) the SPY-PHI System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography. The SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older. The SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures. Upon interstitial administration of SPY AGENT™ GREEN, the SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.
Operating Principle	Full color visible light and NIR fluorescence video imaging. The cameras (VIS+NIR) in the Imaging Head capture the fluorescent image under near infrared light illumination or a color image under white light illumination. The Image Processing Unit receives the video signal from the Imaging	Full color visible light and NIR fluorescence video imaging. The CMOS camera in the Imaging Head captures the fluorescent image under near infrared light illumination or a color image under white light illumination. The VPI receives the video signal from the Imaging Head and

	Head and processes and outputs the video image to a medical grade video monitor and/or video recorder.	processes and outputs the video image to a medical grade video monitor and/or video recorder.
Major Components	**HD system:** Image Processing Unit (OPTO-CAM2100), Imaging Head (OPTO-CHD3100E/OPTO-CHD3100H) **4K system:** Image Processing Unit (OPTO-CAM214K), Imaging Head (OPTO-CHD314KE)	Imaging Head/Imager (HH9030), Video Processor/Illuminator (PC9001)
Image modes	White light image – White light image is displayed in full color. GF image – NIR fluorescence is superimposed in pseudo-color (green) on a white light image SF image – In Segmented Fluorescence (SF) image, a high-definition white light image is displayed in full color with NIR fluorescence overlaid in on a color scale. The pseudo-color of fluorescence will change according to the fluorescence brightness. Parallel display image - The white light image, GF image, SF image, grayscale fluorescent image are displayed on the same screen, with the small image on the left side and the large image as the main image. The default main image is the white light image and can be changed through the menu to the image of other display modes.	White Light Mode - White light image is displayed in full color. Overlay Mode - an NIR fluorescence image is superimposed in pseudo-color (green) on a white light image. Color Segmented Fluorescence (CSF) - white light image is displayed in grayscale with NIR fluorescence overlaid in a color scale. Increasing fluorescence levels transition from blue to yellow to red. SPY mode - an NIR fluorescence image is displayed in grayscale.
Prescription/ Over-the-counter use	Prescription	Prescription
Environment of Use	Hospital	Hospital
Video Output Signals	HD system: SDI, DVI, CVBS, S-VIDEO 4K system: DVI, HDMI, 4×3G-SDI, 12G-SDI	HD-SDI, 3G-SDI, DVI
Image Resolution	HD system: 1920×1080p 4K system: 1920×1080p / 3840×2160p / 4096×2160p	1920×1080p
Sensor Type	CMOS	CMOS
Light source	Visible (VIS): Light-emitting diodes Near infrared (NIR): Light-emitting diodes, wavelength 785nm	Visible (VIS): Light-emitting diode array Near infrared (NIR): NIR laser diode, wavelength 805 nm
Power supply	Mains powered	Mains powered

Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 62471 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60825-1
Design	The light source of the subject device is located in the Imaging Head itself.	The light source is located in the VPI and transmits light through a light guide cable.

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. The test results demonstrated that the proposed device complies with the following standards:

- *IEC 60601-1:2005+A1:2012; ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance (HD system)*
- *IEC 60601-1:2005+A1:2012+A2:2020; ANSI/AAMI ES60601-1:2005 + A2:2010 (R2012) + A1:2012+A2:2021 Medical electrical equipment Part 1: General requirements for basic safety and essential performance (4K system)*
- *IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- *IEC 60601-2-57:2011 Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*
- *IEC 62471:2006 Photobiological safety of lamps and lamp systems*

The software of the proposed device was validated as Moderate level of concern (LoC) in accordance with the following guidance documents: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

Performance testing and animal testing were also conducted on the subject device and demonstrate that the proposed system performs according to specifications and functions as intended.

VIII. Conclusions

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