February 18, 2023

Guangdong OptoMedic Technologies, Inc.
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518100
China

Re: K221861
Trade/Device Name: FloNavi Endoscopic Fluorescence Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, IZI
Dated: January 13, 2023
Received: January 17, 2023

Dear Joyce Yang:

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,

Jianting Wang -S

Jianting Wang
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)*
K221861

Device Name
FloNavi Endoscopic Fluorescence Imaging System

Indications for Use *(Describe)*
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.

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.

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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510(k) Summary - K221861

Date of Summary prepare: February 7, 2023

1. Submission Sponsor

Applicant Name:	Guangdong OptoMedic Technologies, Inc.
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2. Submission correspondent

Name:	Shenzhen Joyantech Consulting Co., Ltd
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Contact person:	Joyce Yang
Phone:	+86-755-86069197
Email:	joyce@cefda.com

3. Device Identification

Trade Name:	FloNavi Endoscopic Fluorescence Imaging System
Common or Usual Name:	Endoscopic Imaging System
Model:	OPTO-CAM214K, OPTO-CHD214KE, OPTO-CHD214KH,OPTO-LED214K; OPTO-CAM2100, OPTO-CHD2100, OPTO-LED2100;
Classification name:	Endoscope and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	GCJ
Device Class:	Class II
Regulation Number:	21 CFR § 876.1500

4. Legally Marketed Predicate Device

Predicate Device:	
Trade Name:	PINPOINT Endoscopic Fluorescence Imaging System
Regulation number:	21 CFR § 876.1500
Regulation class:	Class II

Regulation name:	Endoscope and accessories
510(k) Number:	K182606
Product Code:	GCJ; IZI
Manufacturer:	Novadaq Technologies ULC.
Reference Device:	
Trade Name:	Image 1 SPIES System
Regulation number:	21 CFR § 876.1500
Regulation class:	Class II
Regulation name:	Endoscope and accessories
510(k) Number:	K160044
Product Code:	FET
Manufacturer:	Karl Storz Endoscopy America, Inc.
Trade Name:	Power LED 175
Regulation number:	21 CFR § 876.1500
Regulation class:	Class II
Regulation name:	Endoscope and accessories
510(k) Number:	K123956
Product Code:	FCW, NTN
Manufacturer:	Karl Storz Endoscopy America, Inc.

5. Device Description

The proposed system, FloNavi Endoscopic Fluorescence Imaging System (FloNavi System) is comprised of an image processing unit, a camera head, and a light source (including a flexible light guide cable).

There are two models of the proposed system. The primary components of each model are provided in Table 1.

Table 1 System Model and primary component

FloNavi Endoscopic Fluorescence Imaging System	Primary component
Model 1	Image Processing Unit: OPTO-CAM214K
	Camera Head: OPTO-CHD214KE/OPTO-CHD214KH
	Light Source: OPTO-LED214K
Model 2	Image Processing Unit: OPTO-CAM2100
	Camera Head: OPTO-CHD2100
	Light Source: OPTO-LED2100

Except slight differences in appearance, other differences between components of either model are shown in Table 2.

Table 2 Comparison between primary components

Image Processing Unit			
Item	**OPTO-CAM214K**		**OPTO-CAM2100**
Video outputs	DVI, HDMI, 4×3G-SDI, 12G-SDI		SDI, DVI, CVBS, S-VIDEO
Video output resolution	4096×2160p, 3840×2160p, 1920×1080p, 50/60Hz		1920×1080p, 720×576i, 50/60Hz
Size (mm)	403*370*150		
Weight (kg)	9±15%		9±15%
Camera Head			
Item	**OPTO-CHD214KH**	**OPTO-CHD214KE**	**OPTO-CAM2100**
Image sensor	4K CMOS sensor assembly		HD CMOS sensor assembly
Focusing mechanism	Manual	Motor-driven	Manual
Weight (kg)	0.6±15%		0.5±15%
Light Source			
Item	**OPTO-LED214K**		**OPTO-LED2100**
Size (mm)	403*370*150		
Weight (kg)	11±15%		11±15%
Light guide cable	Diameter: 4.5mm		Diameter: 4.8 mm

FloNavi Endoscopic Fluorescence Imaging System is capable of providing real-time endoscopic visible and near-infrared fluorescence imaging.

During surgical procedures, FloNavi may be operated to provide visualization similar to that provided by conventional imaging systems used in surgical endoscopy. The area of interest is illuminated with visible light from the light source and the resulting reflecting light is imaged by the camera and displayed on the video monitor. When used with the VIS-only laparoscopes, the System is only capable of the conventional mode of visualization described herein.

To provide NIR fluorescence imaging, FloNavi is used with the imaging agent, indocyanine green (ICG). The patient is injected with ICG imaging agent. The ICG fluoresces when illuminated through the laparoscope with NIR excitation light from the light source, and the fluorescence response is then imaged with the camera, processed and displayed on a video monitor.

The proposed system is designed to be used with rigid endoscopes, monitors and other ancillary equipment. The compatible rigid endoscope is O-Mec laparoscopes 690 Series (Model: 690-331030H), which was cleared under K201151.

Intended Use/ Indications for Use

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.

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.

6. Technological characteristics comparison

Table 3 Technological characteristics comparison

Comparison item	Subject Device (K221861)	Predicate Device(K182606)
Product Name	FloNavi Endoscopic Fluorescence Imaging System	PINPOINT Endoscopic Fluorescence Imaging System
Product Code	GCJ	GCJ, IZI
Regulation Number	21 CFR § 876.1500	21 CFR § 876.1500
Classification	Class II	Class II
Type of use	Prescription Use	Prescription Use

Comparison item	Subject Device (K221861)	Predicate Device(K182606)
Intended use & Indications for Use	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. 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.	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 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 user	Physicians	Physicians
Environment of use	Healthcare facility/hospital	Healthcare facility /hospital
Single use / Reusable	Reusable	Reusable
Sterile /non-sterile	Marketed as non-sterile	Marketed as non-sterile
Device System components	- Image Processing Unit - Camera Head - Light Source	- Endoscopic video processor / illuminator (VPI) - Laparoscope

Comparison item		Subject Device (K221861)	Predicate Device(K182606)
		- Light Guide Cable	- Camera head - Light guide cable
Video output signals		OPTO-CAM214K: DVI, HDMI, 4×3G-SDI, 12G-SDI	HD-SDI, DVI
		OPTO-CAM2100: SDI, DVI, CVBS, S-VIDEO	
Video output resolution		OPTO-CAM214K: 4096×2160p; 3840×2160p; 1920×1080p	1920×1080
		OPTO-CAM2100: 1920×1080p; 720×576i	
Voltage		110-240V~	100-240V~
Frequency		50/60 Hz	50/60 Hz
Power consumption		Image Processing Unit: 150VA Light Source: 200VA	300VA
Image sensors		OPTO-CHD214KE/OPTO-CHD214KH: 4K CMOS sensor assembly	CMOS HD sensor assembly
		OPTO-CHD2100: HD CMOS sensor assembly	
Aspect ratio		16:9	16:9
Light sources		- Visible (VIS): Light-emitting diode array - Near infrared (NIR): NIR laser diode	- Visible (VIS): Light-emitting diode array - Near infrared (NIR): NIR laser diode
Light guide cable	Transmission spectrum	Visible + NIR	Visible + NIR
	Fiber diameter	OPTO-LED214K: 4.5mm; OPTO-LED2100: 4.8 mm	4.9 mm
	Length	3 m/3.5m	3 m
	Sterilization	Autoclave	Autoclave
Type of protection against electric shock (as per IEC 60601-1)		Class I	Class I

Comparison item	Subject Device (K221861)	Predicate Device(K182606)
Degree of protection against electric shocks (as per IEC 60601-1)	CF-type	CF-type
Laser classification (as per IEC 60825-1)	Class 3R	Class 3R
Radio frequency emissions (as per CISPR 11)	Group 1, Class A	Group 1, Class A

Summary of Technological Characteristics:

As shown in the comparison table, the proposed system and its predicate has the same intended use and indications for use and similar technological characteristics.

7. Summary of non-clinical testing

The non-clinical test results demonstrated that the proposed device complies with the following standards:

- AAMI/ANSI ES 60601-1:2005/(R)2012 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60825:2014 Safety of laser products – Part 1: Equipment classification and requirements was assessed and showed that subject device is a Class 3R laser device.
- IEC 62471:2006 Photobiological safety of lamps and lamp systems

Performance testing was conducted on imaging performance and light source performance to support the marketing claims and to confirm that safety and effectiveness of the FloNavi Endoscopic Fluorescence Imaging System is at least equivalent to the predicate device.

8. Brief discussion of clinical tests

No clinical tests were performed.

9. Conclusions

The subject device and the predicate device have the same intended use, similar technological characteristics. The technological differences will not cause safety and effectiveness problems for the subject device as compared to its predicate device. Performance tests demonstrate that the FloNavi Endoscopic Fluorescence Imaging

System performs according to specifications and functions as intended. Therefore, the proposed system is substantially equivalent to its predicate device.