Guangdong OptoMedic Technologies, Inc.
Jane Guo
Regulatory Affairs Manager
Suite 503, Building A, Golden Valley
Intellicreation Community, No. 2 Yonganbei Street
Foshan, Guangdong 528200
China

February 2, 2023

Re: K221781
Trade/Device Name: Image Processing Unit, Model: OPTO-CAM104K; Camera Head, Model: OPTO-CHD104KH
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 4, 2023
Received: January 5, 2023

Dear Jane Guo:

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,

Colin K. Chen -S

for

Long Chen, Ph.D.
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)*
K221781

Device Name
Image Processing Unit: OPTO-CAM104K;
Camera Head: OPTO-CHD104KH

Indications for Use *(Describe)*
Image Processing Unit is intended to be used with compatible laparoscopes, camera heads, light sources, monitors, and other ancillary equipment for visualization, image recording and documentation during laparoscopic procedures.

Endoscopic Camera Head is intended to be used with compatible laparoscopes, image processing unit, and other ancillary equipment for visualization, image recording and documentation during laparoscopic procedures.

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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K221781

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: July 13, 2022

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:	Jane Guo Regulatory Affairs Engineer Tel: +86 (757) 8670 2920 Email: guoweijuan@optomedic.com
Secondary Contact Person:	Alice Lau Regulatory Affairs Engineer Tel: +86 (757) 8670 2920 Email: liuli@optomedic.com

II. Device Identification

Device Trade Name:	Image Processing Unit; Camera Head
Common or Usual Name:	Endoscopic Camera System
Model:	Image Processing Unit: OPTO-CAM104K Camera Head: OPTO-CHD104KH
Regulation Name:	Endoscopes and accessories
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Product Code:	GCJ

III. Predicate Device

510(k) Number: K131953

Product Name: Imagel SPIES
The predicate device has not been subject to a design-related recall.

IV. Device Description

The Endoscopic Camera System comprises the Image Processing Unit, the Camera Head (including the objective lens), power supply cord and video cables. The Camera Head with integrated cable can be connected to the Image Processing Unit through the LEMO interface.

During surgical procedures, the Endoscopic Camera System is used to provide real-time visible imaging similar to that provided by conventional imaging system used in surgical endoscopy. The area of interest is illuminated with visible light from the light source and the resulting reflected light is collected by a variety of laparoscopes that are attached to the camera head via equipment coupler. The camera head receives optical image from the connected laparoscope and converts optical image into electronic signal using the incorporated image sensor. The Image Processing Unit serves as the control center of the system and should be connected to a compatible light source in order to provide visualization. It can be connected to a 4K video monitor via one of the video cables provided to display image in real time: DVI cable, HDMI cable, 12G-SDI cable, and 3G-SDI cable.

The proposed system is a reusable device and provided non-sterile. The Camera Head should be cleaned and high-level disinfected prior to the first use and after every subsequent use. The recommended compatible Light Source is OPTO-LED104K (510k exempted, product code: NTN).

V. Indications for Use

Image Processing Unit (hereafter referred to as "IPU") is intended to be used with compatible laparoscopes, camera heads, light sources, monitors, and other ancillary equipment for visualization, image recording and documentation during laparoscopic procedures.

Endoscopic Camera Head is intended to be used with compatible laparoscopes, image processing unit, and other ancillary equipment for visualization, image recording and documentation during laparoscopic procedures.

VI. Comparison of Technological Characteristics with The Predicate Device

Table 1 General Comparison

Description	**Subject Device**	**Predicate Device (K131953)**
Regulation Number	21 CER 876.1500	21 CER 876.1500
Product Code	GCJ	FET
Device class	Class II	Class II
Indication for use	Image Processing Unit (hereafter referred to as "IPU") is intended to be used with compatible laparoscopes, camera heads, light sources, monitors, and other ancillary equipment for visualization,	The Imagel SPIES is a camera control unit (CCU) for use with camera heads or video endoscopes for visualization, image recording and documentation during general endoscopic and microscopic procedures.

	image recording and documentation during laparoscopic procedures. Endoscopic Camera Head is intended to be used with compatible laparoscopes, image processing unit, and other ancillary equipment for visualization, image recording and documentation during laparoscopic procedures.	
Prescription/ Over-the-counter use	Prescription	Prescription
Testing	ANSI/AAMI ES 60601-1: 2005+A2 (R2012) +A1 IEC 60601-1-2:2014 IEC 60601-2-18:2009 ASTM D4169-16 AAMI TIR 30:2016 AAMI TIR 12:2020	IEC 60601-1 IEC 60601-1-2
Dimensions	IPU: 422mm(L)×370mm(W)×149 mm(H) Camera Head: 92mm(L)×39mm(W)×50mm(H)	Image1 S Connect TC200 ： 30.5cm×5.4cm×32.0cm（W×H×D） TH 100&TH 101: 100mm×48mm×38mm(L×H×W) TH 103: 88mm×47mm×35mm(L×H×W) TH 104: 100mm×49mm×39mm(L×H×W)
Weight	IPU：9Kg±15% Camera Head: 400(g)±20	Image1 S Connect TC200: 2.1kg Image1 S H3-Link TC300: 1.86kg Image1 S X-Link TC301: 1.86kg TH100: 270g TH101: 270g TH103: 227g TH104: 299g
Power supply	110-240V AC, 50/60Hz	100-120VAC，50/60Hz 200-240VAC，50/60Hz
Video Output	3G-SDI×4 HDMI ×1 DVI ×1	2×DVI-D 1×3G-SDI

	12G-SDI ×1	
Signal output format	4096×2160p, 3840×2160p, 1920×1080p,50Hz/60Hz	1920×1080p，50/60Hz
Sensor	4K CMOS sensor assembly	3×1/3”

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:

- ANSI/AAMI ES 60601-1: 2005+A2 (R2012) +A1 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014, 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
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems.
- AAMI TIR 30:2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable 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

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 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 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.