June 26, 2024

Zhuhai Dipu Medical Technology Co., Ltd.
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, 518000
China

Re: K233840
Trade/Device Name: Endoscopic Fluorescence Camera System (DPM-ENDOCAM-03PF)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, IZI
Dated: [NOTE: Use date of most recent supplement]
Received: May 29, 2024

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 (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.

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: 2024.06.26 18:41:34 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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.

510(k) Number *(if known)*
K233840

Device Name
Endoscopic Fluorescence Camera System (DPM-ENDOCAM-03PF)

Indications for Use *(Describe)*
Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Fluorescence Camera System is intended to provide real-time endoscopic visible and near-infrared fluorescence visualization. The 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, using near-infrared imaging.
Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Fluorescence Camera System is intended to be 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 K233840

Date of Summary prepare: June 25, 2024

1. Submission Sponsor

Applicant Name:	Zhuhai Dipu Medical Technology Co., Ltd.
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2. Submission correspondent

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3. Device Identification

Trade Name:	Endoscopic Fluorescence Camera System
Common or Usual Name:	Endoscopic Imaging System
Model:	DPM-ENDOCAM-03PF
Classification name:	Endoscope and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	GCJ, IZI
Device Class:	Class II
Regulation Number:	21 CFR § 876.1500

4. Legally Marketed 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.

5. Device Description

The proposed system, Endoscopic Fluorescence Camera System (DPM-ENDOCAM-03PF) is comprised of a 4K video processor (DPM-ENDOCAM-03P-MF), a 4K camera head (DPM-ENDOCAM-03P-CAM), Endoscope (DPM-ENDOSCOPE-0130/DPM-ENDOSCOPE-0100), a cold light source (DPM-LIGHT-03) and a light guide cable (DPM-FB-01).

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

During surgical procedures, the system 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, the system 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.

6. Intended Use/ Indications for Use

Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Fluorescence Camera System is intended to provide real-time endoscopic visible and near-infrared fluorescence visualization. The 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, using near-infrared imaging.

Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Fluorescence Camera System is intended to be used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

7. Technological characteristics comparison

Table 1 Technological characteristics comparison

Comparison item	Subject Device	Predicate Device(K182606)	Comments
Product Name	Endoscopic Fluorescence Camera System	PINPOINT Endoscopic Fluorescence Imaging System	/
Product Code	GCJ, IZI	GCJ, IZI	Same
Regulation Number	21 CFR § 876.1500	21 CFR § 876.1500	Same
Classification	Class II	Class II	Same
Type of use	Prescription Use	Prescription Use	Same
Intended use & Indications for Use	Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Fluorescence Camera System is intended to provide real-time endoscopic visible and near-infrared fluorescence visualization. The 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, using near-infrared imaging. Upon intravenous administration and use of an ICG consistent with its approved label, the Endoscopic Fluorescence Camera System is intended to be 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 nearinfrared imaging. Fluorescence imaging of biliary ducts with the PINPOINT System is intended for use with standard of care white light, and when indicated, intraoperative	Same

Comparison item	Subject Device	Predicate Device(K182606)	Comments
		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	Same
Environment of use	Healthcare facility/hospital	Healthcare facility /hospital	Same
Single use / Reusable	Reusable	Reusable	Same
Sterile /non-sterile	Marketed as non-sterile	Marketed as non-sterile	Same
Device System components	- Video Processor - Camera Head - Endoscope - Light Source - Light Guide Cable	- Endoscopic video processor / illuminator (VPI) - Laparoscope - Camera head - Light guide cable	Same
Video output signals	DVI, HDMI, SDI	HD-SDI, DVI	Similar
Video output resolution	4096×2160p; 3840×2160p; 1920×1080p	1920×1080	Similar
Voltage	100-230V~	100-240V~	Similar
Frequency	50/60 Hz	50/60 Hz	Same
Power consumption	Video Processor: 350VA Light Source: 200VA	300VA	Similar

Comparison item	Subject Device	Predicate Device(K182606)	Comments
Image sensors	4K CMOS sensor assembly	CMOS HD sensor assembly	Similar
Aspect ratio	16:9	16:9	Same
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	Same
Light guide cable	Transmission spectrum: Visible + NIR	Transmission spectrum: Visible + NIR	Same
	Sterilization: Autoclave	Sterilization: Autoclave	Same
Imaging agent	SPY AGENT GREEN	SPY AGENT GREEN	Same
Type of protection against electric shock (as per IEC 60601-1)	Class I	Class I	Same
Degree of protection against electric shocks (as per IEC 60601-1)	CF-type	CF-type	Same
Laser classification (as per IEC 60825-1)	Class 3R	Class 3R	Same
Radio frequency emissions (as per CISPR 11)	Group 1, Class A	Group 1, Class A	Same

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.

8. 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
- ISO 8600-1:2015 Endoscopes - Medical endoscopes and endotherapy devices -- Part 1: General requirements
- ISO 8600-3:2019 Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-4:2014 Endoscopes - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
- ISO 8600-5:2020 Optics and photonics - Medical endoscopes and endotherapy devices - Part 5 Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics: Determination of optical resolution of rigid endoscopes with optics

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 Endoscopic Fluorescence Camera System is at least equivalent to the predicate device. The in vivo fluorescence imaging study on animal model was performed to examine/detect corresponding regions in order to simulate the clinical use, study the imaging effect, and verify the safety and effectiveness.

9. Brief discussion of clinical tests

No clinical tests were performed.

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