U.S. FOOD & DRUG ADMINISTRATION

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July 24, 2025

Wuxi Hisky Medical Technologies Co., Ltd.
℅ Jarvis Wu
AI Regulatory Solutions Lead
PureVision Ai, Inc. (dba Pure Global)
111 Town Square Place, Suite 1203
Jersey City, NJ 07310
USA

Re: K243711
Trade/Device Name: Confocal Microprobe Imaging System (BrightP980); Confocal Microprobe Imaging System (BrightP960); Confocal Microprobe Imaging System (BrightP880); Confocal Microprobe Imaging System (BrightP860); Confocal Microprobe Imaging System (BrightP780); Confocal Microprobe Imaging System (BrightP750); Confocal Microprobe Imaging System (BrightP680); Confocal Microprobe Imaging System (BrightP660); Confocal Microprobe Imaging System (BrightP600); Confocal Microprobe Imaging System (BrightP580); Confocal Microprobe Imaging System (BrightP280); Confocal Microprobe Imaging System (BrightP200); Confocal Microprobe Imaging System (BrightP160); Confocal Microprobe Imaging System (BrightP100); Confocal Microprobe Imaging System (BrightX66); Confocal Microprobe Imaging System (BrightP900)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: June 26, 2025
Received: June 27, 2025

Dear Jarvis Wu:

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,

Jessica Carr -S

Jessica Carr, PhD
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)*

K243711

Device Name

Confocal Microprobe Imaging System (BrightP980);
Confocal Microprobe Imaging System (BrightP960);
Confocal Microprobe Imaging System (BrightP880);
Confocal Microprobe Imaging System (BrightP860);
Confocal Microprobe Imaging System (BrightP780);
Confocal Microprobe Imaging System (BrightP750);
Confocal Microprobe Imaging System (BrightP680);
Confocal Microprobe Imaging System (BrightP660);
Confocal Microprobe Imaging System (BrightP600);
Confocal Microprobe Imaging System (BrightP580);
Confocal Microprobe Imaging System (BrightP280);
Confocal Microprobe Imaging System (BrightP200);
Confocal Microprobe Imaging System (BrightP160);
Confocal Microprobe Imaging System (BrightP100);
Confocal Microprobe Imaging System (BrightX66);
Confocal Microprobe Imaging System (BrightP900)

Indications for Use *(Describe)*

The Confocal Microprobe Imaging System can enter the human body cavity or surgical channel through an endoscope, allowing confocal laser imaging of the microstructure of tissues, including but not limited to the identification of cells, vessels and their organization or architecture.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary
# K243711

Date Prepared: 2025.07.24

## I. Submitter

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Jarvis Wu. Mr
AI Regulatory Solutions Lead
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Pure Global

## II. Device Information

| | |
|---|---|
| Trade Name: | Confocal Microprobe Imaging System |
| Common Name: | Confocal Optical Imaging |
| Classification: | Class II |
| Product Code: | OWN |

## III. Predicate and Reference Devices

| | |
|---|---|
| Predicate Device: | Cellvizio 100 Series System with Confocal Miniprobes |
| 510(k) number: | K191144 |
| Common Name: | Confocal Optical Imaging |
| Classification: | Class II |
| Product Code: | OWN |
| Subsequent Product Codes: | GCJ, GWG |

| | |
|---|---|
| Reference Device: | Cellvizio 100 Series System with Confocal Miniprobes |
| 510(k) number: | K172844 |
| Common Name: | Confocal Optical Imaging |
| Classification: | Class II |
| Product Code: | OWN |

## IV. Indications for Use

The Confocal Microprobe Imaging System can enter the human body cavity or surgical channel through an endoscope, allowing confocal laser imaging of the microstructure of tissues, including but not limited to the identification of cells, vessels and their organization or architecture.

## V. Device Description

The working principle of Confocal Microprobe Imaging System is based on probe-based confocal laser endomicroscopy technology (pCLE). The system combines confocal technology and fiber beam imaging technology. The fiber Optic Microprobe can enter the human cavity through the endoscopic working channel and contact the tissue cells through the object lens at the front end of the Fiber Optic Microprobe. The imaging principle of the device is as follows:

The laser scanning beam emitted by the laser in the Laser Scanning System forms a light source through the grating pinhole and is transmitted to the focal plane of the fluorescent labeled tissue cells through the Fiber Optic Microprobe. The fluorescent substance in the measured tissue cell emits fluorescence under the excitation of the laser. The fluorescence signal is collected by Fiber Optic Microprobe front end object lens and transmitted through the fiber beam microprobe to the detecting hole and then is transmitted to the photomultiplier tube (PMT) of the Photoelectric detector and then to the host for signal analysis and processing. Finally, the image is formed on the computer monitoring screen after software processing.

Light emitted at the top and bottom of the focal plane of the tested tissue produces a large diameter spot (much larger than that of the detecting hole) at the detecting hole, thus only a very small part of the light can be received by the detector through the detecting hole. Moreover, the larger the distance from the focal plane of the object lens, the larger the diffuse spot produced by the non-targeted tissue in the detecting hole and the lesser energy passes through the detecting hole (from 10% to 1%, slowly close to 0%), thus the weaker the unwanted signal is generated on the detector, and smaller the impact is caused by non-targeted tissue. Because confocal microscopy only images the focal plane of the target tissue, it effectively avoids the interference of diffracting light and scattered light, so that it has a higher resolution than ordinary microscopy and has been widely used in biology.

## VI. Technological Comparison

The following Table 1 provides a summary of the subject device Confocal Microprobe Imaging System compared to the predicate device, Cellvizio 100 Series System with Confocal Miniprobes (K191144) and Reference Predicate Cellvizio 100 Series System with Confocal Miniprobes (K172844) which have been legally marketed in the U.S. The attributed being compared including the intended use and the technological characteristics, the differences between the subject device and the predicate device are justified and will not raise new risksin regard to the safety and effectiveness.

***Table 1 – Comparison Table of the Subject Device and Predicate Device***

| **Attribute** | **Subject:**<br>**Confocal Microprobe ImagingSystem**<br>**(K243711)** | **Primary Predicate**<br>**Cellvizio 100 Series System with Confocal Miniprobes (K191144)** | **Similarities/**<br>**Differences** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **Product Code** | OWN | OWN, GCJ, GWG | Same |
| **RegulatoryClass** | II | II | Same |
| **Regulation Number** | 21 CFR 876.1500 | 21 CFR 876.1500<br>21 CFR 882.1480 | all 3 devices fit in the regulation of 21 CFR 876.1500, except the probes ofthe subject device do not provide visualization within thecentral nervous system, meaning that regulation number 21 CFR 882.1480 is not applicable. |
| **Intended Use** | The Confocal Microprobe Imaging System can enter the human body cavity or surgical channel through an endoscope, allowing confocal laser imaging of the microstructure of tissues,including, but not limited to, the identification of cells, vessels and their organization or architecture. | Cellvizio® 100 Series System with Confocal Miniprobes™ is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues, including, but not limited to, the identification of cells and vessels and their organization or architecture.<br><br>The CranioFlex™ Confocal Miniprobe™ is indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.<br><br>The GastroFlex™ UHD and ColoFlex™ UHD Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories.<br><br>The AlveoFlex™ Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories.<br><br>The CholangioFlex™ (or | All 3 devices have the same intended purpose, except, the probes of the subject device donot provide visualization withinthe central nervous system. |

| | | | |
|---|---|---|---|
| | | GastroFlex™ M) series of Confocal Miniprobes™ is intended to allow imaging of the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories.<br><br>The AQ-Flex™ 19 Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., gastrointestinal tracts and respiratory tracts accessed by an endoscope or endoscopic accessories, including through endoscopic needles.<br><br>The CystoFlex™ (F, UHD R) and UroFlex™ B Confocal Miniprobe™ are intended to allow imaging of anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.<br><br>The CelioFlex™ UHD 5 Confocal Miniprobe™ is intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures | |
| **Minimum Bending Radius** | 20mm | 35mm | Same |
| **Maximum Tensile Load ofMicroprobe** | < 500g | < 500g | Same |
| **Maximum Tensile Load of Connector** | < 1000g | < 1000g | Same |
| **Maximum Pressure Resistance ofFiber Bundle** | < 1000g | < 1000g | Same |

| | | | |
|---|---|---|---|
| **MicroprobeAnti-fluid Ingress Rating** | IPX7 | IPX7 | Same |
| **Applied Part** | BF type | BF type | Same |
| **Laser Wavelength** | 488nm ±2nm | 488nm ±2nm | Same |
| **Laser Classification** | Class 2 | Class 2M | Similar.<br>Both Class 2 and Class 2M laser are considered as relatively low risk. This doesnot affect the safety or substantial equivalence of the devices. |
| **Laser Mode** | Continuous<br>Pulsed (at power-on scanningmode) | Continuous | Similar.<br>The laser difference mode does not affect the safety or substantial equivalence of the devices. |
| **Max FrameRate** | ≥120 frames/second | 12 frames/second | Similar.<br>Higher frame rate allows the device capture images or videos at higher speeds. Thisdoes not affect the safety or substantial equivalence of the devices. |
| **Contain sodium fluorescein** | No | Yes | Similar<br>Subject Device does not contain sodium fluorescein same with Reference Predicate Cellvizio 100 Series System with Confocal Miniprobes (K172844) |

**Comparison Analysis**

The information in this submission established that the Confocal Microprobe Imaging System has the same intended use and similar technological characteristics as the predicate device. All performance testing met acceptance criteria. Therefore, the Subject Device is substantially equivalent to the predicate device.

## VII. Biocompatibility

The biocompatibility evaluation for the device was conducted in accordance with Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing includes the following tests:

- ISO 10993-5 :2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 :2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization

- ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Test for irritation
- ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

## VIII. Reprocessing and Shelf-Life

Cleaning, Disinfection and Sterilization Validation of subject device has been conducted in accordance with:

- ISO17664-1 ： 2021 Processing of health care products -Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
- ASTM F3208-20 Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
- FDA Final Guidance (2015) – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- ANSI /AAMI ST98-2022: Cleaning validation of health care products-Requirements for development and validation of a cleaning process for medical devices
- AAMI TIR12:2020 (R2023) – Guide for designing, testing and labeling reusable medical devices for reprocessing
- ASTM D4169-23e1 – Performance Testing of Shipping Containers and Systems
- Fatigue Test and Accelerate Aging Test in accordance with the internal technical requirements

## IX. EMC and Electrical Safety Testing

Testing including electrical safety, mechanical safety, thermal safety, EMC and performance have been conducted to the subject device in accordance with the following standards and the device has demonstrated safety and good performance under normal operating conditions:

- IEC 60601-1:2005+A1:2012+A2:2020 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (Edition 3.2, consolidated Aug 2020)
- IEC 60601-2-18:2009 – Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (3rd Edition, 2009)
- IEC 60601-1-2:2014+AMD1:2020 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests (Edition 4.1, EMC Standard)
- IEC TS 60601-4-2:2024 – Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (Technical Specification, replaces TR 60601-4-2:2016)
- IEC 60825-1:2014 – Safety of laser products – Part 1: Equipment classification and requirements (3rd Edition), including Technical Corrigendum 1 (2008) and Interpretation Sheets 1 & 2 (2007)

## X. Performance Testing

Performance Verification Test has been conducted in accordance with the internal performance requirements stated in the Performance Validation Scheme (HRD0003932 & HRD0004124)

- Validation on Confocal microbe Imaging System whether to meet the requirements of expected performance（HRD0004280）
- Validation on the performance of Confocal Microprobe Imaging System after simulated transport test（HRD0004282）;
- Validation on the performance of Different Types of Fiber Optic Microprobes (HRD0004283);

The above validation indicators include Appearance and structural requirements, Technical

Performance Requirements Fiber length, Field of view, Horizontal resolution, Depth of Observation, Frame rate, Fiber Optic Microprobe performance, Functional Requirements, Power supply voltage adaptation range, Continuous working hours, Laser light source index, and Maximum dispersion angle of microprobe.

## XI. Software and Cybersecurity

Confocal Microprobe Imaging System, has been verified and validated in accordance with FDA software validation guidance: "General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002". Software documentation for moderate level of concern per the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
The subject device has been assessed in accordance with the FDA Guidance Cybersecurity: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff Document issued on September 27, 2023.

## XII. Conclusion

The validations and testing have demonstrated that the subject device Confocal Microprobe Imaging System is substantially equivalent to its predicate device when used as intended.