July 24, 2026

LIMIS Development B.V.
Kelsey Van Abbema
QA/RA Manager
Henri Dunantweg 2
Leeuwarden, 8934AD
Netherlands

Re: K254180
Trade/Device Name: PerfusiX-Imaging
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: June 24, 2026
Received: June 24, 2026

Dear Kelsey Van Abbema:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

SHANIL P. HAUGEN -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K254180 |

Please provide the device trade name(s).

PerfusiX-Imaging

Please provide your Indications for Use below.

PerfusiX-Imaging device is intended to be used only in combination with third party camera heads, rigid surgical endoscopes, monitors, accessories, and other ancillary equipment employed for surgical endoscopic diagnosis, treatment and video observation.

PerfusiX-Imaging device enables real-time visual assessment of vessels, blood flow and related tissue perfusion by means of laser speckle contrast imaging (LSCI), during minimally invasive surgery (laparoscopy) of the gastrointestinal tract, using the device incorporated laser light illumination and video processor.
The device is not intended for standalone use.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

LIMIS

# 510(k) SUMMARY (21 CFR 807.92)

## 1. General Information

| | |
|---|---|
| Submitter Name: | LIMIS Development B.V. |
| Submitter Address: | Henri Dunantweg 2,<br>8934AD, Leeuwarden,<br>The Netherlands |
| Contact Person: | Kelsey van Abbema<br>Manager, Quality Assurance and Regulatory Affairs |
| Contact Information: | Email: kelsey.vanabbema@limis.com |
| | Phone: +31 58 2866971 |
| Submission Type: | Traditional 510(k) |
| Date Prepared: | December 18th, 2025 |

## 2. Subject Device

| | |
|---|---|
| Proprietary Name | PerfusiX-Imaging |
| Device Common Name | Light Source, Imaging Module, Light Cable |
| Device Model Number | 904.000 |
| Device Classification Name | Endoscopic Video Imaging System / Component, Gastroenterology-Urology |
| Regulation Number | 21 CFR 876.1500 |
| Product Code | OWN |
| Device Classification | II |
| Review Panel | Gastroenterology/Urology |
| Premarket Review | Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices (OHT3) |

## 3. Predicate Device and Reference Device

| | Predicate Device | Reference Device |
|---|---|---|
| Proprietary Name | ActivSight Intraoperative Imaging System | Karl Storz ICG Imaging System |
| 510(k) Number | K203550 | K232857 |
| Device Classification Name | Confocal Optical Imaging | Confocal Optical Imaging |
| Regulation Number | 21 CFR 876.1500 | 21 CFR 876.1500 |
| Product Code | OWN | OWN, GWG |
| Device Classification | II | II |

# 4. Device Description

PerfusiX-Imaging is an accessory to existing commercial surgical laparoscope systems, including cameras and video processor units. PerfusiX-Imaging provides real-time endoscopic laser speckle contrast imaging (LSCI). These imaging features allow surgeons to visually assess vessels, blood flow, and tissue perfusion (using Laser Speckle Contrast Imaging). Laser Speckle Contrast Imaging is enabled through a switch on the device. These visualization features are available for surgeons to use during minimally invasive surgery. PerfusiX-Imaging is intended to be used in a surgical environment.

PerfusiX-Imaging consists of the following:

- ***PerfusiX-Imaging Video Processor and Light Source,*** *which is placed in the light path between the laparoscope video processor, enabling surgeons to switch between white light imaging (WLI) and laser speckle contrast imaging (LSCI). PerfusiX-Imaging is furthermore looped into the video signal path to process and display the LSCI image on the Operating Room screen.*

# 5. Indications for Use

PerfusiX-Imaging is intended to be used only in combination with third party camera heads, rigid surgical endoscopes, monitors, accessories, and other ancillary equipment employed for surgical endoscopic diagnosis, treatment and video observation.

PerfusiX-Imaging enables real-time visual assessment of vessels, blood flow and related tissue perfusion by means of laser speckle contrast imaging (LSCI), during minimally invasive surgery (laparoscopy) of the gastrointestinal tract, using the device incorporated laser light illumination and video processor. The device is not intended for standalone use.

# 6. Substantial Equivalence

PerfusiX-Imaging (subject) is substantially equivalent to ActivSight's capability to visualize blood flow and perfusion through speckle laser illumination (predicate).

The subject device and predicate device have nearly identical Indications for Use. Both devices provide real-time endoscopic Laser Speckle Contrast Imaging during minimally invasive surgery. Both are indicated to enable surgeons to visually assess blood flow and tissue perfusion in the abdominal cavity.

Differences between the two devices are that PerfusiX-Imaging operates on a different light wavelength, 639nm for PerfusiX-Imaging versus 852nm for ActivSight. Furthermore, ActivSight provides a separate camera with the system whereas PerfusiX-Imaging uses the 3$^{rd}$ party camera of the laparoscopic tower.

## Table 6.1: Comparison to Predicate

| | PerfusiX-Imaging | ActivSight Intraoperative Imaging System (K K203550) - *Predicate* | Karl Storz ICG Imaging System (K232857) - *Reference* |
|---|---|---|---|
| **Intended Use** | Confocal Optical Imaging (OWN) | Confocal Optical Imaging (OWN) | Confocal Optical Imaging (OWN) |
| **Indications for Use** | PerfusiX-Imaging is intended to be used only in combination with third party camera heads, endoscopes, monitors, accessories, and other ancillary equipment employed for endoscopic diagnosis, treatment and video observation. PerfusiX-Imaging enables real-time visual assessment of vessels, blood flow and related tissue perfusion by means of laser speckle contrast imaging (LSCI), during minimally invasive surgery (laparoscopy) of the gastrointestinal tract, using the device incorporated laser light illumination and video processor. The device is not intended for standalone use. | The ActivSight Intraoperative Imaging System (ActivSight) is intended to provide real- time endoscopic fluorescence and near infrared imaging. ActivSight enables surgeons to visually assess vessels, blood flow, and related tissue perfusion using fluorescence and near infrared imaging, and at least one of the major bile ducts (cystic duct, common bile duct, or common hepatic duct) using fluorescence, all during minimally invasive surgery.<br><br>Fluorescence imaging of biliary ducts with ActivSight is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for stand-alone use for biliary duct visualization. | Upon intravenous administration and use of ICG consistent with its approved label, the Karl Storz Endoscopic ICG 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 (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the Karl Storz Endoscopic ICG 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. Additionally, the KARL STORZ Endoscopic ICG System enables surgeon to perform minimally invasive cranial neurosurgery in adults and pediatrics and endonasal skull base surgery in adults and pediatrics > 6 years of age using standard endoscopic visible light |

| | | | |
|---|---|---|---|
| | | | as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging. The Karl Storz VITOM ICG System is intended 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 in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures in adults and pediatrics. |

| Technical Specifications | | | |
|---|---|---|---|
| | PerfusiX-Imaging | ActivSight Perfusion (K203550) – *Predicate* | Karl Storz ICG Imaging System (K232857) – *Reference* |
| Mode of Action | Laser Speckle | Laser Speckle / Fluorescence | Fluorescence |
| Contrast Agent | None | None / ICG | ICG |
| Information Presentation Format | Viridis color heatmap signal overlayed on black/white video signal | Laser Speckle: Heatmap signal overlayed on red/green/blue (RGB) or heatmap signal only<br><br>*For ICG:*<br>*Green Signal overlayed on red/green/blue (RGB)* | Displayed image is either the VIS light image or the NIR image. For the NIR image, the user has three presentations of the ICG imagery to choose from: a. Overlay: The white light image is overlaid with the NIR image. The NIR image could either by blue or green b. Intensity Map: The white light image is overlaid with color transformed NIR image. c. Monochromatic: The NIR image is indicated by the color white against a dark background. |
| White light source | Third party light source | Third party light source | Karl Storz Power LED RUBINA® light source (TL400) |
| White light camera | Third party camera | Third party camera | Karl Storz Image1 S™ |
| White light image processing | Third party processing unit | Third party processing unit | Karl Storz Image1 S™ |
| LSCI/ICG Light Source(s) | Coherent 639 nm laser | Coherent 852 nm laser | NIR Filtered LED Output: 720-810 nm |
| Laser Power Rating | Class 3B out of light cable, class 2 out of scope. | Class 3R out of Light Cable, class 1 out of scope | N/A |
| Light Capture | 3rd party laparoscopic system with RGB camera | IR sensitive camera | IR sensitive camera |
| Resolution | Full HD (1080p) | Full HD (1080p) | Ultra HD (4k) |
| Framerate | 60 fps | 60 fps | 60 fps |
| Power requirements | AC mains powered | AC mains powered | AC mains powered |
| Data output | SDI | DVI | 12G/3G-SDI, DisplayPort, DVI-D |
| User interface | Touchscreen and monitor | Touchscreen and monitor | Touchscreen and monitor |

# 7. Performance Data

Safety and performance of PerfusiX-Imaging have been evaluated and verified in accordance with design specifications and applicable performance standards, including risk management, basic safety and essential performance, electromagnetic disturbances, human factors and usability, software lifecycle processes, and safety of laser products.

LIMIS Development has performed design validation in animal study, comparatively visualizing blood flow and perfusion in specific structures against the reference device ICG mode (Karl Storz ICG Imaging System). In a similar way to the validation study performed by the predicate device (ActivSight) on their respective reference device ICG mode. A clinical evaluation of PerfusiX-Imaging was conducted to support use of the device in the gastrointestinal tract.

The following performance testing has also been conducted:

Basic safety and essential performance testing completed in accordance with

- *IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020: Medical Electrical Equipment- Part 1: General Requirements for Basic Safety and Essential Performance. Testing indicates that the proposed device conforms to this standard.*
- *Electrical safety and electromagnetic compatibility testing completed in accordance with IEC 60601-1-2:2014, 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. Testing indicates that the proposed device conforms to this standard.*
- *Human factors and usability testing completed in accordance with IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 for use in conjunction with IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020, and IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 Medical Devices -Application of Usability Engineering to Medical Devices- Evaluation and reporting. Testing indicates that the proposed device presents no unacceptable risk to the user during its intended use, and that the device conforms to this standard.*
- *Software development and software life cycle processes competed in accordance with IEC 62304:2006+AMD1:2015 Medical Device Software - Software Life Cycle Processes, Evaluation, Testing, and Reporting. Testing indicates that the proposed device conforms to this standard.*
- *Laser safety testing completed in accordance with IEC 60825-1 Ed. 3.0 b:2014 Safety of Laser Products- Part 1: Equipment Classification and Requirements. Testing indicates that the proposed device conforms to this standard.*
- *Safety of endoscopic equipment testing completed in accordance with IEC 60601-2-18:2009 for use in conjunction with IEC 60601-1:2005 Medical Electrical Equipment- Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment. Testing indicates that the proposed device conforms to this standard.*

The results of these studies demonstrate that the proposed device is as safe and effective as the predicate.

## 8. Conclusion

Based on the information provided in this premarket notification and based on a comparison to the indications for use, performance testing, and technological characteristics of the predicate, PerfusiX-Imaging is shown to raise no new questions of safety and efficacy, and is substantially equivalent to the ActivSight Intraoperative Imaging System.