



June 24, 2025

Hypervision Surgical
Jaco Jacobs
Chief Operating Officer
London Institute for Healthcare Engineering
100 Lambeth Palace Road
London, SE1 7AR
United Kingdom

Re: K250268
Trade/Device Name: HyperSnap Surgical System (HSS)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: SFE, FET, MUD
Dated: January 24, 2025
Received: January 30, 2025

Dear Jaco Jacobs:

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,

YAN FU-S

Digitally signed by YAN
FU-S
Date: 2025.06.24
17:58:03 -04'00'

for Tanisha Hithe
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

Indications for Use

510(k) Number (if known)

K250268

Device Name

HyperSnap Surgical System (HSS)

Indications for Use (Describe)

The HyperSnap Surgical System is a real-time video camera system utilising computational hyperspectral imaging in the visible spectrum. The system is intended to be used intraoperatively to relay a standard RGB video feed used for visualisation alongside corresponding tissue oxygenation information presented as a corresponding two-dimensional real-time video feed.

The system is intended for use as an adjunctive monitor of the haemoglobin oxygen saturation of blood (StO₂) in the superficial tissue in the surgical field of view.

The HyperSnap Surgical System may help identify patients at risk of tissue ischaemia. The system is indicated for use in all populations for open and minimally invasive general surgical applications utilising compatible surgical telescopes (exoscopes and rigid endoscopes).

The prospective clinical value of measurements made with StO₂ has not been demonstrated in disease states.

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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K250268 - HYPERSNAP® SURGICAL SYSTEM

1. Submitter's Information

Manufacturer	Hypervision Surgical Ltd
Address	London Institute for Healthcare Engineering, 100 Lambeth Palace Road, London, SE1 7AR
Contact	regulatory@hypervisionsurgical.com
Company Contact Person	Dr Jaco Jacobs
Date Prepared	24 th June 2025

2. Subject Device

Device Trade Name	HyperSnap Surgical System (HSS)
Device Common Name	Video Imaging System
Classification Regulation Number	21 CFR 876.1500
Classification Regulation Name	Endoscope and Accessories
Device Classification	Class II
Device Product Code	SFE, FET, MUD

3. Predicate and Reference Devices

Herein we will make use of the following devices. Our strategy for demonstrating substantial equivalence to our predicate device will be via a comparison of performance of the subject device to that of the reference device. The chosen predicate device used a similar approach to gain marketing authorisation.

Device Type	Device	Marketing Authorisation	Product Code
Predicate	FUJIFILM EX-0, VP-7000	K203717	GCJ, FET, NTN, PEA, MUD, NWB
Reference	Moor VMS-OXY Tissue Oxygenation and Temperature Monitor	K112826	MUD

4. Device Description

4.1. Safer Technologies Program Designation

The HSS was granted a Safer Technologies Program (STeP) designation by the US Food and Drug Administration (FDA) in 2024, a voluntary program for certain medical devices that are reasonably expected to significantly improve the safety of currently available treatments.

4.2. General Description

Hyperspectral imaging (HSI) is an optical imaging modality that carries information about tissue properties, facilitating objective tissue characterisation without the need for any exogenous contrast agent. HSI is non-invasive, non-contact, and does not make use of ionising radiation.

The HSS is an HSI system that seamlessly integrates into surgical workflows to provide critical, but currently unavailable, tissue property information during surgery. The HSS provides for visualisation of real-time tissue oxygenation saturation (StO₂) information alongside conventional red-green-blue (RGB) visualisation. Additionally, the mean StO₂ value within a user-defined ROI is reported.

Imaging is displayed at video rate ensuring instant surgeon feedback and intra-operative tissue assessment to facilitate surgical guidance and decision making.

The HSS is an artificial intelligence (AI) / machine learning (ML) enabled device. Training data for the deep learning algorithm comprises high resolution medical imaging datasets which collectively offer representative spatial and spectral variation across the intended target tissues and surfaces.

4.3. Core Components of the HyperSnap Surgical System

The core components of the HSS include, amongst others, a hyperspectral camera, the HyperSnap Camera, a computational workstation, the Camera Control Unit (CCU), the Camera Electrical Isolator and Camera Electrical Isolator Power Supply. The HyperSnap Camera is a lightweight surgical camera with a snapshot hyperspectral imaging sensor. Our surgical imaging technology exploits highly optimised algorithms and software to leverage snapshot HSI hardware for the extraction of advanced optical properties of observed tissues.

The camera can be securely mounted but is easily manoeuvrable, allowing for controlled mobilisation and immobilisation of the imaging system by a single operator without the need for an assistant. The CCU runs the HyperSnap Software which implements a deep learning approach for super-resolution and reconstruction of acquired snapshot hyperspectral images.

4.4. Supported Accessories

Supported accessories include the Insufflator, Light Source and Light Guide. Peripheral input/output devices include the Surgical Display, Foot Control and Surgical Keyboard.

The HSS is compatible with different Surgical Telescopes allowing for use in both open and laparoscopic surgical procedures for general surgical specialities. Surgical Telescopes connect to the HyperSnap Camera via a Coupler.

Sterility in the surgical field is maintained by using a Surgical Drape; a sterile surgical gauze is used as a Calibration Target prior to the surgical procedure.

Finally, a Surgical Trolley and mandatory Isolating Transformer are used to securely house the system components and supported accessories.

4.5. Surgical Stack

The HyperSnap Surgical System comprises the core components and accessories. When fully configured with all necessary accessories, it forms a surgical stack capable of supporting both laparoscopic and open surgical procedures.

5. Statement of Intended Use

5.1. Indications for Use

The HyperSnap Surgical System is a real-time video camera system utilising computational hyperspectral imaging in the visible spectrum. The system is intended to be used intraoperatively to relay a standard RGB video feed used for visualisation alongside corresponding tissue oxygenation information presented as a corresponding two-dimensional real-time video feed.

The system is intended for use as an adjunctive monitor of the haemoglobin oxygen saturation of blood (StO₂) in the superficial tissue in the surgical field of view.

The HyperSnap Surgical System may help identify patients at risk of tissue ischaemia. The system is indicated for use in all populations for open and minimally invasive general surgical applications utilising compatible surgical telescopes (exoscopes and rigid endoscopes).

The prospective clinical value of measurements made with StO₂ has not been demonstrated in disease states.

5.2. Contraindications

The HSS has no known contraindications.

5.3. Intended Patient Population

The HSS is indicated for use in all populations indicated for general surgical applications (laparoscopic or open surgery).

5.4. Intended Users

The HSS is intended to be used by surgeons. Operating theatre staff, i.e., medical assistants with relevant specialist qualifications like a scrub nurse or circulating nurse, may optionally assist the surgeon.

5.5. Operating Environment

The HSS is intended to be used in a professional healthcare environment, i.e. operating room or operating theatre.

6. Comparison of Technological Characteristics

6.1. Similarities

Both devices relay real-time imaging information to be used intraoperatively. Both devices are intended to be used by trained physicians to visually assess vessels and other critical structures of interest. Both devices relay additional tissue property information, namely the haemoglobin oxygen saturation of blood in superficial tissue in an area under observation in patients at risk of ischaemic states.

6.2. Differences

The subject device uses hyperspectral imaging to non-invasively quantify tissue oxygenation metrics. The subject device uses snapshot hyperspectral technology that enables the capture of hyperspectral information in real-time. However, while snapshot hyperspectral cameras enable real-time imaging, this is achieved by spatial multiplexing of spectral information. The subject device employs highly optimised algorithms for real time reconstruction and recovery of spatio-spectral information, reconstruction of RGB information, and estimation of tissue properties such as tissue oxygen saturation, StO₂. The predicate device provides additional optical imaging modes: blue light imaging, linked colour imaging, white light imaging, in addition to oxygen saturation imaging information. When in oxygen saturation imaging mode, StO₂ images are quantified from the differences in the absorption coefficient in the visible light region between oxy- and deoxy-haemoglobin using a small number of wavelengths. The unit alternately emits select wavelengths of light synchronously, from which images are acquired with an RGB colour charge coupled device mounted at the tip of the endoscope. An StO₂ image is subsequently created by performing a nonlinear transformation on the images acquired that correspond to the illumination induced by the different wavelength LEDs. The StO₂ images are displayed by assigning the StO₂ level to the RGB display colour of the monitor in 1% increments, with the StO₂ level of 100% as red, 50% as yellowish green, and 0% as dark blue. The subject device is a hyperspectral surgical camera whilst the predicate is an endoscopic video imaging camera.

6.3. Substantial Equivalence Comparison

This table compares the subject and predicate devices.

Property	Subject Device	Predicate Device
Premarket Notification	K250268	K203717
Manufacturer	Hypervision Surgical Ltd	FUJIFILM Corporation
Device Name	HyperSnap Surgical System	FUJIFILM EX-0, VP-7000
Generic Name	Video imaging system	Endoscopic video imaging system
Codified Regulation	21 CFR 876.1500	21 CFR 876.1500
Product Codes	SFE, FET, MUD	GCI, FET, NTN, PEA, MUD, NWB
Use Environment	Operating room (operating theatre)	Operating room (operating theatre)
Intended User	Surgeon	Surgeon
Indications for Use	The HyperSnap Surgical System is a real-time video camera system utilising computational hyperspectral imaging in the visible spectrum. The system is intended to be used intraoperatively to relay a standard RGB video feed used for visualisation alongside corresponding tissue oxygenation information presented as a corresponding two-dimensional real-time video feed. The system is intended for use as an adjunctive monitor of the haemoglobin oxygen saturation of blood (StO₂) in the superficial tissue in the surgical field of view. The HyperSnap Surgical System may help identify patients at risk of tissue ischaemia. The system is indicated for use in all populations for open and minimally invasive general surgical applications utilising compatible surgical telescopes (exoscopes and rigid endoscopes). The prospective clinical value of measurements made with StO₂ has not been demonstrated in disease states.	The VP-7000 unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using a FUJIFILM medical endoscope and light source together with monitor, recorder, and various peripheral devices. The Image Processing Unit EX-0 is an optional module intended for use as an adjunctive monitor of the haemoglobin oxygen saturation of blood in superficial tissue of the endoscopic observation image area in patients at risk for ischaemic states. This product may be used on all patients requiring endoscopic examination when using a FUJIFILM medical endoscope, video processor and light source together with monitor, recorder, and various peripheral devices. The prospective clinical value of measurements made with OXEI has not been demonstrated in disease states.

Property	Subject Device	Predicate Device
Patient Population	All patients indicated for laparoscopic or open surgery	All patients requiring endoscopic examination
Surgical Telescopes	Compatible exoscopes and rigid endoscopes	Endoscope with flexibility adjuster
Imaging Modes	White light imaging (RGB) and StO2	Different modes are supported: blue light imaging, linked colour imaging, white light imaging, and oxygen saturation imaging
White Light Imaging	Yes	Yes
FICE Mode	No	Yes
BLI Mode	No	Yes
BLI Bright Mode	No	Yes
LCI Mode	No	Yes
StO2	Two-dimensional colour coded images of StO2% of the endoscopic observation imaging area	Two-dimensional colour coded images of StO2% of the endoscopic observation imaging area
Image Sensor	Mosaic CMOS hyperspectral imaging sensor on HyperSnap Camera	RGB colour charge coupled device mounted at the tip of the endoscope
Power Rating	Camera Control Unit 100–240V AC 50/60Hz 10–5A	EX-0, VP-7000 100–240V AC 50/60Hz 1.2–0.7A
	Camera Electrical Isolator Power Supply 100–240V AC 50/60Hz 0.4A/115V AC – 0.25A/230V AC	
Light Source	Compatible broad band white light	5 LED lights are controlled independently. Blue LED creates short wavelength light, red/green/blue LEDs are combined as white light
Calibration	Compatible sterile gauze	As per manufacturer's instructions

Property	Subject Device	Predicate Device
Cybersecurity	Cybersecurity in line with FDA consensus standard TIR 57	FDA guidance documents <i>Content of Premarket Submissions for Management of Cybersecurity in Medical Devices</i>
Software	Software in line with FDA consensus standard IEC 62304	IEC 62304 and FDA guidance documents <i>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</i>
Artificial Intelligence / Machine Learning	Evaluated as per <i>Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations</i>	Not an AI/ML-enabled device
Risk	Risk management per FDA consensus standard ISO 14971	Information not publicly available
Human Factors	Usability engineering per FDA consensus standard IEC 62366-1	Information not publicly available
Photobiological Safety	Evaluated as per FDA consensus standard IEC 62471	Information not publicly available
Electromagnetic Compatibility	Evaluated as per FDA consensus standards IEC 60601-1-2 and AIM 7351731 Additional performance testing to demonstrate compatibility with common electromagnetic emitters	Evaluated as per FDA consensus standard IEC 60601-1-2
Electrical, Mechanical, Thermal	Evaluated as per FDA consensus standards IEC 60601-1, IEC 60601-1-6 and IEC 60601-2-18	Evaluated as per FDA consensus standards IEC 60601-1, IEC 60601-1-6, IEC 60601-2-18, and IEC 60825-1
Interoperability	Interoperability evaluation in line with <i>Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices</i>	Information not publicly available

Property	Subject Device	Predicate Device
Bench Testing	StO2 measurement performance of the subject and reference devices was compared with a dissolved oxygen meter as a gold standard using 12 different blood-based phantoms, simulating the optical properties of different tissues and surface types that may be monitored by the subject device. The spatial resolution of the subject device was assessed using a USAF-1951 resolution test target and an ISO 12233 e-SFR test target, in line with the ISO 8600-5 and ISO 12233 standards. The RGB reconstruction performance of the subject device was assessed on a range of Spectralon diffuse colour standards.	StO2 measurement performance of the subject and reference devices was compared with a dissolved oxygen meter as a gold standard using 7 different blood-based phantoms, simulating the optical properties of different tissues that may be monitored by the subject device.
Animal Testing	Three GLP animal studies were conducted using a laparoscopic approach and subsequent conversion to open surgery to evaluate safety, performance, and usability of the subject device in a representative in-vivo model according to the predefined endpoints. The StO2 outputs reported by the subject device were compared against a reference device.	Three animal studies were conducted: one laparoscopic, one endoscopic and one for open surgery. The StO2 outputs reported by the predicate device were compared against a reference device.

7. Consensus Standards

HVS has identified the following standards which are applicable to the product realisation process. We list process as well as product-based standards utilised and include the recognition number for FDA consensus standards.

Standard	Consensus Recognition Number	Conformity Assessment
IEC 62304	13-79	Declaration of conformity
ISO 14971	5-125	Declaration of conformity
TIR 57	13-83	Declaration of conformity
CVSS 3.0	13-116	Declaration of conformity
ANSI/NEMA HN 1-2019 (MDS2)	13-123	Declaration of conformity
IEC 62366-1	5-129	Declaration of conformity
IEC 62471	12-249	Declaration of conformity
IEC 60601-1	19-4	Declaration of conformity
IEC 60601-1-2	19-36	Declaration of conformity
IEC 60601-1-6	5-132	Declaration of conformity
IEC 60601-2-18	9-114	Declaration of conformity
AIM 7351731	19-45	Declaration of conformity
IEC TR 60601-4-2	19-19	Declaration of conformity
ISO/CIE 11664-6	9-148	General use
ISO 8600-5	9-131	General use

8. Performance Data

In this section we include a brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. The StO₂ measurement function was evaluated via extensive and comparative bench testing and animal testing. Performance testing established that the subject device may be used as a conventional RGB visualisation system as well as an adjunctive monitor of the haemoglobin oxygenation saturation of blood in superficial tissue.

8.1. AI/ML Technical Validation

Technical validation of the deep learning-based super-resolution and reconstruction algorithm confirmed that all predefined technical performance criteria were met. Evaluation across benchmark datasets demonstrated superior image reconstruction performance relative to baseline methods, as indicated by improvements in peak signal-to-noise ratio (PSNR), structural similarity index measure (SSIM), and reconstruction fidelity. Furthermore, the reconstruction fidelity metric was validated against previously unseen representative in-vivo performance data, supporting the algorithm's generalisability and robustness in clinically representative settings.

8.2. Bench Performance Testing

8.2.1. Tissue Oxygenation

StO₂ measurement performance of the subject and reference devices was compared with a dissolved oxygen meter as a gold standard using 12 different blood-based phantoms, simulating the optical properties of different tissues that may be monitored by the subject device. The subject device was used, with supported accessories, as labelled, to quantify the StO₂ level. Results demonstrated that the subject device performs comparably to the reference device, K112826, with respect to monitoring StO₂ levels.

8.2.2. Spatial Resolution

The spatial resolution performance of the subject device was assessed using a USAF-1951 resolution test target and an ISO 12233 e-SFR test target, in line with the ISO 8600-5 and ISO 12233 standards. Results demonstrated that the subject device achieved good spatial resolution performance, displaying satisfactory repeatability and reproducibility against predetermined acceptance criteria across repeated acquisitions and varying HSS configurations (i.e., different supported Surgical Telescopes).

All predetermined and objective acceptance criteria were met to confirm the validity of the technical performance of the spatial resolution of the RGB output of the subject device.

8.2.3. Colourimetry

The RGB reconstruction performance of the subject device was assessed on a range of Spectralon diffuse colour standards. Results demonstrated that the subject device achieved satisfactory colour reconstruction performance across the range of Spectralon diffuse colour standards.

All predetermined and objective acceptance criteria were met to confirm the validity of the technical performance in terms of colourimetry of the RGB output of the subject device.

8.3. Animal Performance Testing

Three GLP compliant animal studies were conducted to evaluate safety, performance, and usability of the subject device in a representative in-vivo model according to the predefined endpoints.

Overall, the safety profile assessment showed that the subject device met all predefined criteria and that the subject device was safe to use when applying the usual principles of laparoscopic surgery.

All endpoints for evaluation of the performance profile were met, notably: the laparoscopic vs open small bowel StO₂; detection of qualitative changes in StO₂ visualised laparoscopically with the subject device during clamping of small and large bowel mesentery; the detection of quantitative changes in StO₂ measured laparoscopically with the subject device during clamping of small bowel and large bowel mesentery; repeatability and reproducibility of StO₂ quantification metrics reported by the subject device as well as demonstration of

adequate RGB visualisation of predefined anatomical structures; and detection of qualitative changes in RGB visualised laparoscopically with the subject device during clamping of small and large bowel.

The usability assessment was favourable as all usability criteria were met and the device could be successfully positioned to enable imaging and focusing to achieve a sharp image of the target tissue.

9. Conclusion

The subject device shares the same intended use and substantially similar indications to the chosen predicate. Any differences herein raise no additional risks, nor do these differences bring up new questions of safety and efficacy of the subject device in relation to the predicate.

The subject device was developed under a quality management system (QMS) in conformity with ISO 13485 and the FDA's own Quality System Regulation (QSR). Furthermore, the FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QSR, providing a similar level of assurance in the quality management system and ability to consistently manufacture devices that are both safe and effective.

HVS cites conformity to FDA recognised consensus standards IEC 62366-1 and ISO 14971 for human factors and safety risk management activities, respectively.

External conformity assessments by certification body (CB) scheme accredited and nationally recognised test laboratories (NRTL) per the following consensus standards demonstrated acceptable basic safety and essential performance of the subject device: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-18 and AIM 7351731. Additional electromagnetic compatibility (EMC) testing, specifically focussed on common electromagnetic emitters, was conducted and demonstrated that there was no degradation in the performance of the subject device.

Photobiological safety evaluation of the supported high intensity Light Source demonstrated a favourable safety profile.

Technical validation of the deep learning-based super-resolution and reconstruction algorithm confirmed that all predefined technical performance criteria were met.

Software was developed and verified under FDA's recognised consensus standard IEC 62304 with additional considerations provided in TIR 57 implemented for a secure software development lifecycle that consistently produces devices and software that provide reasonable assurance of cybersecurity.

Extensive bench and GLP compliant animal performance testing, with predefined endpoints and acceptance criteria, demonstrated that the performance profile of the subject device is satisfactory.

The subject device successfully met all acceptance criteria and passed validation against user needs.

The aforementioned, when taken in totality, supports the notion that the subject device is at least as safe and at least as effective as the predicate. HVS considers the devices substantially equivalent.