SurgVision GmbH
Daniela Mahan
Regulatory Affairs Manager
Kistlerhof Strasse 70, Building 79
Munich, Bavaria 81379
Germany

February 25, 2022

Re: K214097
Trade/Device Name: Explorer Air II
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: December 15, 2021
Received: December 28, 2021

Dear Daniela Mahan:

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 and Part 809); 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,

Neil R.P. Ogden, M.S.
Assistant Director, THT4A4
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)*
K214097

Device Name
EXPLORER AIR® II

Indications for Use *(Describe)*
Upon intravenous administration and use of an ICG (Indocyanine green for Injection) consistent with its approved label, the EXPLORER AIR® II is used in capturing and viewing fluorescent images for the visual assessment of blood flow and tissue perfusion, before, during, and after vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgeries. The EXPLORER AIR® II is indicated for use in adult and pediatric patients one month of age and older.

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Device Identification

Trade or Proprietary Name:	*EXPLORER AIR® II*
Common or Usual Name:	Angiographic X-Ray System
Classification Name:	Angiographic X-Ray System
Device Class:	Class II
Classification:	21 CFR 892.1600
Product Code:	IZI
Manufacturer:	SurgVision GmbH Kistlerhof Strasse 70, Building 79 Munich 81379 Germany
Contact Name:	Ms. Daniela Mahan, Esq., RAC Regulatory Affairs Manager +49 15785116008 daniela.mahan@surgvision.com
Date Prepared:	February 10, 2022

Predicate Devices

The subject *EXPLORER AIR® II* is the same or similar to the following device:

Product Name	Manufacturer	510(k) Number	Date of FDA Clearance
SPY Elite Intraoperative Perfusion Assessment System	Novadaq Technologies ULC., now a part of Stryker	K182907	January 23, 2019

Device Description

EXPLORER AIR® II is a fluorescence imaging system, which enables users to visually assess blood flow to evaluate tissue perfusion and tissue-transfer circulation. It can be used on any part of the body during plastic, reconstructive, gastrointestinal, and organ transplant surgeries.

EXPLORER AIR® II consists of an imaging system that contains two cameras (one (1) for fluorescence, one (1) for color images) suspended by an articulated arm attached to a trolley. A touch screen and secondary monitor are also mounted on the trolley.

EXPLORER AIR® II enhances the surgeon's vision with use of near infrared fluorescence (NIR) imaging. The technology is based on the exposure of the tissue of interest to light after fluorescent dye such as indocyanine green (ICG) has been administered to the patient. The *EXPLORER AIR® II* visualizes fluorescence excited by infrared light (740-760nm) and emitted in the band centered around 800nm. After image acquisition, the composite image (overlay of fluorescence and color images) is displayed along with the fluorescent and color images. The user can tag and compare images, play the recorded videos, and export the selected files.

The *EXPLORER AIR® II* must be used with *EXPLORER AIR® Sterile Drape* for use under sterile conditions. The *EXPLORER AIR® Sterile Drape* is manufactured by Exact Medical Manufacturing, Inc., and has been cleared in K101689.

Indications for Use

Upon intravenous administration and use of an ICG (Indocyanine green for Injection) consistent with its approved label, the *EXPLORER AIR® II* is used in capturing and viewing fluorescent images for the visual assessment of blood flow and tissue perfusion, before, during, and after vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgeries. The *EXPLORER AIR® II* is indicated for use in adult and pediatric patients one month of age and older.

Technological Characteristics

As was established in this submission, the subject *EXPLORER AIR® II* is the same or similar to the predicate device cleared by the FDA for commercial distribution in the United States. The subject device was shown to be the same or similar and has the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. Both the subject and predicate devices utilize the same mode of imaging – near infrared fluorescence imaging, with ICG as the imaging agent, used in the hospital operating room. The proposed and predicate devices have the same basic components – an imaging console/trolley, camera able to detect fluorescence, monitors and software. Further comparison is provided in ***Table 1*** below.

Specification/ Property	Predicate Device SPY Elite Intraoperative Perfusion Assessment System (K182907)	Subject Device EXPLORER AIR® II	Conclusion
Image of the device			Similar
Device Class	Class II	Class II	Same
Product Code	IZI	IZI	Same
Regulation Number	21 CFR 892.1600	21 CFR 892.1600	Same
Device Classification Name	Angiographic X-Ray System	Angiographic X-Ray System	Same
Device Description summary	The SPY Elite System is an angiographic fluorescence imaging system which is used for nearinfrared fluorescence imaging during open surgery, with indocyanine green (ICG) as the imaging agent. The SPY Elite System allows surgeons to capture, review, print, and archive high-quality fluorescence images of blood flow in vessels, micro-vessels, tissue and organ perfusion in real time during various surgical procedures.	The *EXPLORER AIR® II* is an angiographic fluorescence imaging system which is used for nearinfrared fluorescence imaging during open surgery, with indocyanine green (ICG) as the imaging agent. The *EXPLORER AIR® II* allows surgeons to capture, review, compare, playback and export high-quality fluorescence images of blood flow in vessels, micro-vessels, tissue and organ perfusion in real time during various surgical procedures.	Same
Intended Use / Indications for Use	Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for Injection, USP), the SPY Elite System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography. The SPY Elite System used with SPY AGENT™ GREEN is indicated for use in adult and pediatric patients one month of age and older.	Upon intravenous administration and use of an ICG (Indocyanine green for Injection) consistent with its approved label, the *EXPLORER AIR® II* is used in capturing and viewing fluorescent images for the visual assessment of blood flow and tissue perfusion, before, during, and after vascular, gastrointestinal, organ transplant, and plastic,	Similar. Slight differences in the wording of the indications for use for describing the same intra-operative situation. These slight differences do not create a new intended use nor a different indication for use. The subject and predicate devices are intended to capture and view fluorescent

	The SPY Elite System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgeries.	micro- and reconstructive surgeries. The *EXPLORER AIR® II* is indicated for use in adult and pediatric patients one month of age and older.	images for the visual assessment of blood flow.
Principle of Operation	NIR light from the illumination module in the imaging console is transmitted to the imaging head via fiber-optic cable. The imaging head is positioned over the patient such that the NIR excitation light is emitted and illuminates the area of interest. When the patient is injected with ICG, the ICG binds to the plasma in the blood and travels to the area of interest through the bloodstream. The NIR excitation light emitted by the SPY Elite imaging device causes the ICG to fluoresce. The fluorescence image signal is processed and simultaneously recorded in computer memory and displayed on the video monitors in real time.	The camera head is positioned over the patient such that the NIR excitation light is emitted and illuminates the area of interest. When the patient is injected with ICG, the ICG binds to the plasma in the blood and travels to the area of interest through the bloodstream. The NIR excitation light emitted by the *EXPLORER AIR® II* causes the ICG to fluoresce. The fluorescence image signal is processed and simultaneously recorded in computer memory and displayed on the video monitors in real time.	Same
Design	- The device is a mobile camera system consisting of a trolley and a camera head suspended on an articulated arm. - The device has two monitors.	- The *EXPLORER AIR® II* is a mobile camera system consisting of a trolley and a camera head which is suspended on an articulated camera head arm. - The device has 2 monitors, a primary touchscreen display for operator use and a secondary display which is the surgeon monitor.	Same
Environment of Use	Hospital	Hospital	Same
Patient Contact	No direct or indirect patient contact.	No direct or indirect patient contact.	Same
Users	Operators trained in the use of fluorescence imaging during surgical procedures.	Trained nurses and surgeons.	Same

System Components	SPY Elite contains a radiation source, a detector (CCD camera), and signal processing software. The major components of SPY Elite are: - Imaging Console - CINEVAQ Software (1x) – Analysis and Comparison Dashboar - CINEVAQ Software (2x) – Analysis Dashboard and Case Management for vascular imaging modality - DICOM Send Software	The *EXPLORER AIR® II* is comprised of: - Trolley - Camara head containing color and fluorescent cameras - Camera arm - Monitors (2) - Software	Similar
Wavelength	White light LED: 830 nm NIR: 805 nm	White light LED: 400 - 700 nm NIR: 740 – 760 nm	Similar. Differences in the light source between the subject and predicate devices do not raise new questions of safety and effectiveness since despite differences in the exact illumination configuration (wavelength, coherence, power), both devices are able to produce near infrared fluorescence images (for example of the dye ICG). *EXPLORER AIR® II* complies with the relevant safety standards with respect to illumination (IEC 62471). *EXPLORER AIR® II* utilized LED-based NIR excitation, which is inherently safer than the laser-based excitation of the SPY Elite System.
Alignment lasers	650 nm (1 mW)	650 nm (0.8 mW)	Similar. The two laser pointers of *EXPLORER AIR® II* are only used to adjust the working distance of the camera head and are switched on only for this purpose. No continuous laser light emission during the procedure.
Working Distance	30 cm	23 cm	Similar. The minor differences in the optic working distance do not raise new questions of safety and effectiveness

			since the working distance is specific for the used optical system / design.
Irradiance at target	29 mW/cm2	19.8 mW/cm2	Similar. Differences in the irradiance between the subject and predicate devices do not raise new questions of safety and effectiveness since despite differences in the exact value the *EXPLORER AIR® II* value is lower than the predicate, but still capable of producing near infrared fluorescence images. *EXPLORER AIR® II* complies with the relevant safety standards with respect to illumination (IEC 62471).
Field of view	13 cm x 18 cm	14 cm x 14 cm	Similar. The minor differences in the field of view do not raise new questions of safety and effectiveness since the working distance plus area is specific for the used optical system / design, and the image output is sufficient for the assessment of perfusion during surgery.
Camera	CCD	CMOS and sCMOS	Similar. *EXPLORER AIR® II* comprises two cameras to acquire the fluorescence image and the color image separately. The sCMOS sensor is part of the fluorescence camera while the CMOS sensor is part of the color camera. This difference has no impact on safety and effectiveness given that both systems are capable of producing near infrared fluorescence images.
Image output	752 x 480 pixels	Fluorescence: 1200 x 1200 pixels Color: 2048 x 2048 pixels	Similar. Image output of the subject device is sufficient for the assessment of perfusion during surgery and therefore does not raise any new questions of safety and performance compared to K182907.

Device Functionalities (image acquisition, enhancement, and display)	(1) Live feed of images displayed on the device's monitors. (2) Playback of recorded videos (3) Color overlays (4) Print/export images	(1) Live feed of images displayed on the device's monitors. (2) Playback and Comparison function of recorded images and videos (3) Composite image (4) Export images	Same
Light source	- Visible light illumination: White light LED - IR illumination: Laser	- Visible light illumination: White light LEDs - IR illumination: NIR LEDs - Two (2) laser pointers for adjusting the working distance to the desired value.	Different. Differences in the light source between the subject and predicate devices do not raise new questions of safety and effectiveness since despite differences in the exact illumination configuration (wavelength, coherence, power), both devices are able to produce near infrared fluorescence images (for example of the dye ICG). *EXPLORER AIR® II* complies with the relevant safety standards with respect to illumination (IEC 62471). *EXPLORER AIR® II* utilized LED-based NIR excitation, which is inherently safer than the laser-based excitation of the SPY Elite System.
Sterile Draping	Yes, draping is required when using the device in a sterile environment. The NOVADRAPE 8000 sterile drape is a custom sterile surgical drape that attaches to the imaging head of the SPY Elite device via a specially designed optical window and sterile tapes and is designed to maintain sterility of the operating field throughout the procedure. The NOVADRAPE 8000 sterile drape is supplied sterile and must be handled aseptically to maintain the sterile filed during surgery.	Yes, draping the *EXPLORER AIR® II* is a mandatory process before using the device in a sterile environment. The *EXPLORER AIR® Sterile Drape* is a custom surgical drape that attaches to the camera head and is designed to maintain sterility of the operating field throughout the procedure. The drape is supplied sterile and is intended for single use only. After use, dispose of the drape.	Similar. Both predicate and subject device require a sterile drape in order to be used in the sterile field. Each device references the compatible drape according to its design.

Contrast Agent	ICG, namely SPY AGENT™ GREEN (Indocyanine green for injection, USP)	ICG	Same

Performance Data

The *EXPLORER AIR® II* was designed and developed by SurgVision in accordance with the applicable requirements and standards to establish performance and safety of the device. Device safety and performance were verified by tests conducted by SurgVision and accredited third party laboratories. The following performance data were provided in support of substantial equivalence.

Electrical safety and electromagnetic compatibility (EMC)

The *EXPLORER AIR® II* was tested in accordance with AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests conformance testing. Test results showed that *EXPLORER AIR® II* conforms to the applicable requirements.

Additionally, *EXPLORER AIR® II* complies with IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems and IEC 60601-2-57 Edition 1.0 2011-01 Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use. An assessment and test according to IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements was conducted resulting in the *EXPLORER AIR® II* to classify as a Class 2 laser system (two lasers for distance adjustment only). Further analysis and application of IEC 60825 to the subject device is not required: the subject device does not utilize the lasers for achieving the intended use. For *EXPLORER AIR® II* the safety of lasers and illumination for the intended use have been checked according to the above referenced standards.

Test results showed that the *EXPLORER AIR® II* meets and conforms to the applicable requirements.

Verification of optical, mechanical and functional requirements

Requirements for optical and mechanical specifications were met via verification by inspection, demonstration and analysis. A summary of results, remarks and pass/fail for each individual requirement was provided for:

- Fluorescent performance
- Physical Properties
- Environmental conditions
- Optical Requirements
- Design and ergonomics
- Usage requirements

- Power supply
- Data export
- Mechanical restrictions

ICG Testing

The *EXPLORER AIR® II* was tested to demonstrate its capability to detect ICG and to determine the limit of detection of fluorescence when measuring ICG in different concentrations. A calculation of the lowest concentration at a specified signal-to-noise ratio (SNR) was tested in three devices, showing consistent results and demonstrating the *EXPLORER AIR® II* detects ICG.

Human Factors Validation

The *EXPLORER AIR® II* was validated to demonstrate it is safe and effective for the intended users and uses, in the intended use environments. The Human Factors Report was performed according to IEC 62366-1 Edition 1.1 2020-06, Medical devices – Part 1: Application of usability engineering to medical devices and IEC 62366-2 edition 1.0 from 2016-04-27, Medical devices – Part 2: Guidance on the application of usability engineering to medical devices. Further information on the planning and identification of all parameters to consider was documented according to the FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff", issued on February 3, 2016.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff" issued on May 11, 2005. The software for this device was considered a "Moderate" level of concern, since a malfunction of the device software could lead to a delay in care if the physician were to rely on *EXPLORER AIR® II* instead of performing a visual assessment of the perfusion in the interested tissue.

Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *EXPLORER AIR® II* has been shown to be as safe, as effective, and to perform as well as the legally marketed predicate device.

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