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

February 28, 2023

Re: K222240
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: January 23, 2023
Received: January 23, 2023

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); 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,

Colin K. Chen -S

for

Jessica Carr
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222240

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.

Upon administration and use of pafolacianine consistent with its approved labeling, the EXPLORER AIR® II is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

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

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:	Februrary 16th, 2023

Predicate Devices

Primary Predicate Device

Product Name	Manufacturer	510(k) Number	Date of Concurrence
EXPLORER AIR II	SurgVision GmbH	K214097	February 25, 2022

Additional Predicate Device

Product Name	Manufacturer	510(k) Number	Date of Concurrence
VS3 Iridium System	Visionsense Ltd. (Medtronic)	K210265	November 22, 2021

Device Description

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) or pafolacianine has been administered to the patient. The *EXPLORER AIR® II* visualizes fluorescence excited by infrared light (740-760nm) and emitted in the band 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.

This Traditional 510(k) premarket notification is to expand the indication for use statement to include the additional cleared infrared dye, pafolacianine, for use with infrared imaging.

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.

Upon administration and use of pafolacianine consistent with its approved labeling, the *EXPLORER AIR® II* is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

Technological Characteristics

The *EXPLORER AIR® II* has the same performance as the primary predicate device *EXPLORER AIR® II* cleared in K214097 and is similar to additional predicate device *VS3 Iridium System* cleared in K210265 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 and pafolacianine as the imaging agents, 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.

Device & Predicate Device(s):	K222240 *EXPLORER AIR® II*	K214097 *EXPLORER AIR® II*	K210265 *VS3 Iridium System*	**Comparison**
General Device Characteristics				
Device class	II	II	II	**Same.**
Product code	IZI	IZI	OWN	**Same as primary** predicate device. **Different from additional** predicate device, however, the code also relates to imaging (Confocal Optical Imaging).
Regulation number	892.1600	892.1600	876.1500	**Same as primary** predicate device. **Different from additional** predicate device, however, this sub-chapter focuses on the endoscopy technique, but the technology is regulated by the generic Angiographic X-Ray System chapter.
Light source	Visible light: White light LED IR: NIR LED	Visible light: White light LED IR: NIR LED	Visible light: White light LED IR: Infrared laser	**Same as primary** predicate device. **Same as additional** predicate device for visible light illumination (LED), but **different for near infrared illumination**. LED-based NIR excitation is inherently safer than the laser-based excitation of the additional predicate device. Both devices are able to produce NIR fluorescence images, supported by comparison test results summarized in the Performance Data section below.
Wavelength	White light LED: 400 - 700 nm IR: 740 – 760 nm	White light LED: 400 - 700 nm IR: 740 – 760 nm	White light LED: 400 - 700 nm IR: 785 nm	**Same as primary** predicate device. **Similar to additional** predicate device regarding IR. Both devices excite pafolacianine within the peak absorption region of its spectrum, supported by comparison test results summarized in the Performance Data section below.
Working distance	23 cm	23 cm	20 – 45 cm	**Same as primary** predicate device. **Similar to additional** predicate device, indicating a range. The differences come from the specific device design.
Irradiance at target	19.8 mW/cm2	19.8 mW/cm2	At 40 cm: 6 mW/cm^2 Max: 47 mW/cm2	**Same as primary** predicate device. **Similar to additional** predicate device, the *EXPLORER AIR® II* is within the range established for the *VS3 Iridium System*.
Mode of imaging	NIR fluorescence	NIR fluorescence	NIR fluorescence	**Same.**
Camera	CMOS and sCMOS	CMOS and sCMOS	Silicon Image Sensor	**Same or Similar**.
Contrast agent	ICG, Pafolacianine	ICG	ICG, Pafolacianine	**Different from primary** predicate device. This submission seeks to add pafolacianine as a second agent, addressing identified risks, mitigations, and their verification. **Same as additional** predicate device.
Input voltage	100-120 V	100-120 V	120 VAC or 230 VAC	**Same.**
Input frequency	50/60 Hz	50/60 Hz	50 Hz @ 230 VAC or 60 Hz @ 120 VAC	**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. The expansion of the indication of the subject device does not change the biocompatibility, electrical safety, electromagnetic compatibility, or cleaning or sterilization from the previous clearance in K214097. Performance of the *EXPLORER AIR® II* with pafolacianine was verified and software validation was conducted to include the additional protocol for imaging pafolacianine.

Pafolacianine Testing

The *EXPLORER AIR® II* was tested to demonstrate its capability to detect pafolacianine at different concentrations. A calculation of the lowest concentration at a specified contrast-to-noise ratio (CNR) was tested in two devices, showing consistent results and demonstrating the *EXPLORER AIR® II* detects pafolacianine.

Additional comparison testing with the secondary predicate device (K210265) was conducted to support substantial equivalence in regards to differences in light source and excitation wavelength. The *EXPLORER AIR® II* was able to visualize lower concentration samples of pafolacianine compared to the additional predicate device, both by analysis of the image contrast (CNR) and by observation of the images.

Human Factors

Human Factors Report was updated to document the inclusion of the new expanded indication for use of the device with pafolacianine. An assessment of user profiles, environment of use, training, user interactions with the device and procedure workflow for the new indication were assessed. It was concluded that all these factors remain the same, and identified risks, mitigations and verification was conducted and found acceptable. Therefore, the *EXPLORER AIR® II* has been found to be safe and effective for the intended users in the intended use environment for the new indication of use of the subject device with pafolacianine.

Software Verification and Validation

Software verification and validation testing were updated and conducted. 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 and draft "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on November 4, 2021. The software for this device was considered a "Moderate" level of concern and "Basic Documentation Level", 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 devices.

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