March 20, 2024

SurgVision GmbH
Daniela Mahan
Quality and Regulatory Affairs Manager
Kistlerhofstrasse 70, Building 79
Munich, 81379 Germany

Re: K234090
Trade/Device Name: EXPLORER AIR® II (8001, 8002, 8003); EXPLORER AIR® Sterile Drape (8004)
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: IZI, OWN
Dated: December 22, 2023
Received: December 22, 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 (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.

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)*

K234090

Device Name

EXPLORER AIR® II (8001, 8002, 8003);
EXPLORER AIR® Sterile Drape (8004)

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:

Contact Details

Manufacturer: SurgVision GmbH
Kistlerhof Strasse 70, Building 79
Munich 81379
Germany

Contact Name: Ms. Daniela Mahan, Esq., RAC
Quality and Regulatory Affairs Manager
+49 15785116008
daniela.mahan@surgvision.com

Device Identification

Device Trade Name: *EXPLORER AIR® II, EXPLORER AIR® Sterile Drape*
Common or Usual Name: Angiographic X-Ray System
Classification Name: System, X-Ray, Angiographic
Classification: 21 CFR 892.1600
Product Code: IZI
Device Class: Class II

Date Prepared: March 19th, 2024

Legally Marketed Predicate Devices

Product Name	Manufacturer	510(k) Number	Product Code
EXPLORER AIR® II	SurgVision GmbH	K222240	IZI

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.

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.

Indications for Use Comparison
The indications for use of the *EXPLORER AIR® II* are the same as the predicate device cleared in K222240.

Technological Characteristics
The subject device *EXPLORER AIR® II* is substantially equivalent to the predicate device cleared by the FDA for commercial distribution in the United States. The subject device is substantially equivalent and has the same technological characteristics to its predicate device through comparison in areas including design, intended use, material composition, and function. The only difference between the *EXPLORER AIR II* device cleared in K222240 and the subject device *EXPLORER AIR II* are the minor differences for HW design 2.2 (due to manufacturability and EOL of certain components), Packaging 2.0 (same materials, improvements for repacking in case of service), and SW 2.2 (OTS updates, image visualization improvements, and removal of alignment step by the user prior to every procedure). All changes were assessed and verified, and no new or different questions on safety or performance were raised.

Non-Clinical Tests and Conclusions
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 three changes in HW, Packaging and SW of the subject device do not change the biocompatibility, electrical safety, electromagnetic compatibility, or cleaning or sterilization from the previous clearance in K222240. Performance of the *EXPLORER AIR® II* was verified and software validation was conducted:

<u>Software Verification and Validation</u>
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 issued on June 14, 2023*. The software for this device requires "Basic Documentation Level", since a malfunction of the device software

could lead to a delay in care if the physician were to rely on the *EXPLORER AIR® II* instead of performing a visual assessment of the perfusion in the interested tissue.

No clinical tests were conducted to support this submission.

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 substantially equivalent to a legally marketed predicate device.

END OF DOCUMENT