April 15, 2022

Ecential Robotics
% Mathilde Saulpic
Quality Assurance & Regulatory Affairs Engineer
Zone Mayencin II, Parc Equation - Bâtiment 1,
2 avenue de Vignate
Gieres, 38610
FRANCE

Re: K220946
Trade/Device Name: SURGIVISIO Device
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: March 29, 2022
Received: April 1, 2022

Dear Mathilde Saulpic:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K220946

Device Name
SURGIVISIO Device

Indications for Use *(Describe)*
The SURGIVISIO device is intended to be used during surgical procedures in which the physician would benefit from the visualization of 2D medical imaging and/or intraoperatively generated 3D medical imaging of anatomical structures or objects with high x-ray attenuation such as bony anatomy or metallic objects. Such procedures include procedures during which the spine, pelvis or articulation structures are visualized.

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

Submitter Information

Submitter: ECENTIAL ROBOTICS
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Date Summary Prepared: 08 April 2022

Summary of the technological characteristics of the device compared to the predicate device

There have been no modifications on indication for use on SURGIVISIO Device since the previously approved submission K202547 & K220627.

This submission aims at adding a new Imaging set: 3D Offset Imaging Set SPX1 accessory, which enables to deport imaging zone regarding the already cleared 3D Imaging Set SPX1 accessory, giving user more flexibility by freeing space around the Patient reference SPX1 and the zone of interest. The new 3D Offset Imaging Set SPX1 accessory will not replace the already cleared 3D Imaging Set SPX1 accessory.

Device Information

Trade or proprietary name:	SURGIVISIO Device
Common or usual name:	Mobile Interventional Fluoroscopic X-ray System
Classification Name:	Interventional Fluoroscopic X-Ray System
Regulation Number:	21 CFR 892.1650 - Image-intensified fluoroscopic x-ray system
Regulatory class:	II
Primary product code:	OWB
Legally marketed device to which equivalence is claimed:	K202547 & K220627 – SURGIVISIO device - Manufacturer: ECENTIAL ROBOTICS (previously SURGIVISIO)
Device Description:	The SURGIVISIO Device is a mobile x-ray system which provides 2D imaging and allows the generation of intraoperative 3D information of high contrast objects and anatomical structures. The system consists of two mobile interconnected units: a mobile C-arm and a mobile viewing Workstation. These units are moved manually and are interconnected by a single cable that provides power and transfer of data and controls. The mobile C-Arm comprises a high voltage generator, foot switches for radiation release, laser target devices, electronics cabinet, collision avoidance system, and a C-shaped structure mounting the X-ray tube assembly and the flat X-ray detector on distal end of the ‘C’. The mobile viewing workstation comprises a computer, an image detector process unit, the main power supply, radiation indicator, dual viewing monitors and a user interface for patient management and image handling.

	The system integrates a Computer Aided Surgery (CAS) feature that supports instruments positioning during surgical procedures. The SPX1 Instruments are a set of dedicated accessories intended to be used in conjunction with the SURGIVISIO Device in order to enable stereotaxic guidance. More specifically, and when used with the 3D imaging, they support the registration of the patient anatomy with the 3D reconstructed image. Submissions K202547/ K220627 consider SPX1 instruments set with the standard 3D Imaging Set SPX1 accessory. This submission aims at clearing a new imaging set accessory possibility: the 3D Offset Imaging Set SPX1 accessory, containing same patient reference and wedges as 3D imaging Set SPX1 accessory already 510(k) cleared, and an offset phantom (new instrument). The principle of use of the Offset Phantom SPX1 is identical to the already 510(k) cleared Phantom SPX1 (belonging to 3D Imaging set). However, the Offset Phantom SPX1 additional value is to offset the imaging area that will be navigated during surgery by 10 cm from the standard configuration. The 3D Imaging Set SPX1 accessory will be considered as the predicate for the 3D Offset Imaging Set SPX1 accessory.
Indication for use:	The SURGIVISIO device is intended to be used during surgical procedures in which the physician would benefit from the visualization of 2D medical imaging and/or intraoperatively generated 3D medical imaging of anatomical structures or objects with high x-ray attenuation such as bony anatomy or metallic objects. Such procedures include procedures during which the spine, pelvis or articulation structures are visualized. Indication for use is the same as the predicate.
Technology comparison	Same as the predicate. The technology is not impacted by the discussed device change, object of this Special 510(K) submission. This is an x-ray system that generates 2D and 3D images of anatomical structures. The 3D Offset Imaging Set accessory is used in combination with the imaging system in the same way than the 3D Imaging Set SPX1 accessory.
Biocompatibility	Same as the predicate. The discussed device change, object of this Special 510(K) submission does not require to re-perform Biocompatibility testing as the raw material, manufacturing processes are the same for 3D Imaging Set SPX1 accessory than for 3D Offset Imaging Set SPX1 accessory.

Electrical Safety Testing	Same as the predicate. The discussed device change, object of this Special 510(K) submission does not impact Electrical Safety.
Performance Testing	Same as the predicate.
Software Testing	Same as the predicate. Software change to enable the identification of the Offset Phantom SPX1 were already taken into account in submission K220627. The clearance of the present Special 510(k) would enable to release the associated functionalities by clearing the associated required instrument. SURGIVISIO software was verified and validated according to IEC 62304 Medical Device Software. Results of these validations and verifications confirm that the SURGIVISIO software complies with its specifications.
Clinical images	Same as the predicate. The discussed device change, object of this Special 510(K) submission does not impact clinical images.
Conclusion	Based upon comparison of devices and performance testing results, SURGIVISIO Device using 3D Offset Imaging Set SPX1 accessory is substantially equivalent to the predicate device.

Devices	SURGIVISIO Device used with 3D Offset Imaging Set SPX1 accessory	SURGIVISIO Device (K202547 & K220627) used with 3D Imaging Set SPX1 accessory
Intended use / Indication for use	The SURGIVISIO device is intended to be used during surgical procedures in which the physician would benefit from the visualization of 2D medical imaging and/or intraoperatively generated 3D medical imaging of anatomical structures or objects with high x-ray attenuation such as bony anatomy or metallic objects. Such procedures include procedures during which the spine, pelvis or articulation structures are visualized.	The SURGIVISIO device is intended to be used during surgical procedures in which the physician would benefit from the visualization of 2D medical imaging and/or intraoperatively generated 3D medical imaging of anatomical structures or objects with high x-ray attenuation such as bony anatomy or metallic objects. Such procedures include procedures during which the spine, pelvis or articulation structures are visualized.
Primary product code	OWB	OWB
Mechanical configuration	Mobile C-Arm	Mobile C-Arm
Movement range	Vertical: Up to 43.5cm Horizontal: Up to 28cm Orbital: 200° Angulation: 180°	Vertical: Up to 43.5cm Horizontal: Up to 28cm Orbital: 200° Angulation: 180°
Movement control	Motor-driven	Motor-driven
kV Range	40 – 120 kV	40 – 120 kV
mA Range	1 – 120 mA	1 – 120 mA
Pulse frequency	1 – 12.5 fps	1 – 12.5 fps
Detector technology	Flat panel, 287mm x 265mm	Flat panel, 287mm x 265mm
Image Matrix Size	1560x1440 pixels 780x720 pixels	1560x1440 pixels 780x720 pixels
X-ray tube technology	Rotating anode 0.3 – 0.8 focal spot	Rotating anode 0.3 – 0.8 focal spot
2D Imaging	2D Fluoroscopic	2D Fluoroscopic
Pulsed Fluoroscopy	Yes	Yes
AERC system	Yes, kv/mA curve types	Yes, kv/mA curve types
3D Imaging	Yes	Yes
Rotating movement for 3D imaging	180°	180°

Devices	**SURGIVISIO Device used with 3D Offset Imaging Set SPX1 accessory**	**SURGIVISIO Device (K202547 & K220627) used with 3D Imaging Set SPX1 accessory**
3D Imaging characteristics	Cylindrical volume: 15 x Ø13 cm Elliptic cylindrical volume: 15 x $Ø_1$16 x $Ø_2$18 cm Resolution 400 x 400 x 400 voxels	Cylindrical volume: 15 x Ø13 cm Elliptic cylindrical volume: 15 x $Ø_1$16 x $Ø_2$18 cm Resolution 400 x 400 x 400 voxels
Monitor cart/Workstation	Yes	Yes
Screen displays	2 Monitors 22" tactile Screen Displays	2 Monitors 22" tactile Screen Displays
Image output format	DICOM	DICOM
LAN network connection	Yes	Yes
Computer Aided Surgery (CAS) interface	Yes, integrated	Yes, integrated
3D Imaging set accessory components	Offset Phantom SPX1 with its ID card Patient reference SPX1 with its ID card Associated wedges	Phantom SPX1 with its ID card Patient reference SPX1 with its ID card Associated wedges
3D Imaging set accessory components packaging	Offset Phantom SPX1 and patient reference with associated wedges packaged in one unique blister Blister Material and reference: PETG & Tyvek 1073B	Phantom SPX1 and patient reference packaged in its own Blister Patient reference SPX1 with associated wedges packaged in its own Blister Blister Material and reference: PETG & Tyvek 1073B
Software workflow	3D Spine Universal workflow	3D Spine Universal workflow

Performance Data

For further information about testing, standards, acceptance criteria and results, please refer to section Design Control Activities Summary.

Nonclinical tests: The following nonclinical tests were performed on the SURGIVISIO Device using 3D Offset Imaging Set SPX1 accessory to demonstrate substantial equivalence of safety and efficacy with the predicate device:

- Design verification activities have been performed for the Offset Phantom SPX1
- Accuracy verification has been conducted at the system level with the 3D Offset Imaging Set SPX1 accessory as intended
- Software verification testing verifying the software requirements has been performed as intended and are already taken into account by the previous 510(k) cleared version (Submission K220627).
- Packaging process validation and verification activities, including Shelf-life validation, have been conducted as intended

Clinical tests: No clinical tests were conducted to demonstrate substantial equivalence.

Conclusions drawn from Performance Data

The SURGIVISIO Device using 3D Offset Imaging Set SPX1 accessory is identical in indications for use and technological characteristics as the proposed predicate device. These aspects, along with the performance testing conducted, demonstrate the substantial equivalence to the SURGIVISIO Device (K202547/ K220627) and that the SURGIVISIO Device using 3D Offset Imaging Set SPX1 accessory does not raise different questions of safety and effectiveness when compared to this predicate.