



March 18, 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: K220627

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 2, 2022
Received: March 4, 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

Indications for Use

510(k) Number (if known)
K220627

Device Name
SURGIVISIO Device

Indications for Use (Describe)

The SURGIVISIO medical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Information

Submitter: eCential Robotics
Zone Mayencin II, Parc Equation – Bâtiment 1
2 avenue de Vignate
38610 Gières
France

Contact Person: Mathilde SAULPIC
Quality Assurance & Regulatory Affairs Engineer
Phone : 0033 4 58 00 35 86
Email: mathilde.saulpic@ecential-robotics.com

Date Summary Prepared: 02 MAR 2022

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 – SURGIVISIO system - 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

	<p>mounting the X-ray tube assembly and the flat X-ray detector on distal end of the 'C'.</p> <p>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.</p> <p>The system integrates a Computer Aided Surgery (CAS) feature that supports instruments positioning during surgical procedures.</p>
Indication for use:	<p>The SURGIVISIO medical 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.</p>
Technology comparison	<p>The technology has not changed. This is an x-ray system that generates 2D and 3D images of anatomical structures.</p>
Biocompatibility	<p>Same as the predicate.</p>
Electrical Safety Testing	<p>Same as the predicate.</p>
Performance Testing	<p>Same as the predicate.</p>
Software Testing	<p>Change of the software version from 1.5.1 to 1.8.1.</p> <p>SURGIVISIO software was verified and validated according to IEC 62304 Medical Device Software.</p> <p>Results of these validations and verifications confirm that the SURGIVISIO software complies with its specifications.</p>
Clinical images	<p>Same as predicated</p>

Conclusion

Based upon comparison of devices and performance testing results, SURGIVISIO software is substantially equivalent to the predicate device.

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

There has been no modifications on indications for use on SURGIVISIO Device since the previously approved submission K202547.

Devices	SURGIVISIO Device	SURGIVISIO System (K202547)
Intended use / Indication for use	The SURGIVISIO medical 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 medical 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

Devices	SURGIVISIO Device	SURGIVISIO System (K202547)
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°
3D Imaging characteristics	Cylindrical volume: 15 x Ø13 cm Elliptic cylindrical volume: 15 x Ø116 x Ø218 cm Resolution 400 x 400 x 400 voxels	Cylindrical volume: 15 x Ø13 cm Elliptic cylindrical volume: 15 x Ø116 x Ø218 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

Performance Data

Nonclinical tests: The following nonclinical tests were performed on the SURGIVISIO Device to demonstrate substantial equivalence of safety and efficacy with the predicate device:

- Software Verification testing verifying the software requirements perform as intended

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

Conclusions drawn from Performance Data

The SURGIVISIO Device is similar 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 system (K202547) and that the SURGIVISIO Device does not raise different questions of safety and effectiveness when compared to this predicate.

1. Device Name

<i>Device Trade Name</i>	<i>Common/Classification Name</i>
SURGIVISIO Device	Common or usual name: Mobile interventional Fluoroscopic X-ray system Classification name: Interventional Fluoroscopic X-ray system, 21 CFR 892.1650 Image-intensified fluoroscopic x-ray system

2. Address and registration

The address of the manufacturer for the SURGIVISIO device is:
ECENTIAL ROBOTICS
Zone Mayencin II, Parc Equation – Bâtiment 1
2 avenue de Vignate
38610 Gières
FRANCE

3. Device class

SURGIVISIO device is a class II device.

4. Predicate device information

The predicate device is SURGIVISIO system, K202547.

5. Labeling and intended use

Labeling is same as predicated.

The SURGIVISIO medical 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.

This is the same intended use as previously cleared for the SURGIVISIO system, K202547.

6. Device description and comparison

A device description can be found in Section 8.

The modification that has been made is a change in software version from 1.5.1 to 1.8.1.

7. Substantial equivalence

The modified SURGIVISIO device is substantially equivalent to the previously SURGIVISIO system K202547 because both devices have the same indication for use and intended use, similar principle of operation, similar technical characteristics, and design.

8. Summary of design control activities

A summary of design control activities for the SURGIVISIO device can be found in section 10.

9. 510(k) summary

A 510(k) summary for the SURGIVISIO device can be found in section 6.

10. Truthful and accuracy certification

A certification of the truthfulness and accuracy of the SURGIVISIO device described in this submission can be found in section 7.