July 6, 2022

Ecential Robotics
Sarah Lefevre-Billard
Zone Mayencin II, Parc Equation - Bâtiment 1,
2 avenue de Vignate
Gieres, 38610
France

Re: K221028
Trade/Device Name: SURGIVISIO Device
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 4, 2022
Received: April 7, 2022

Dear Sarah Lefevre-Billard:

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,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K221028

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

The SURGIVISIO Device through its freehand navigation feature is intended as an intraoperative guidance system to enable open or percutaneous computer-assisted surgery.
It is indicated for conditions of the spine in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical bony structure can be identified relative to the intraoperatively generated 3D image of the anatomy provided by the SURGIVISIO Device.
It is indicated to precisely position the Navigated Targeting Needle SPX1 during general spinal procedures with a posterior approach.

The SURGIVISIO Device through its robotic guidance feature is intended for the positioning of instrument holders or tool guides to be used by surgeons to guide the Spine CoBot instruments during general spinal surgery.
Guidance is based on an intra-operative plan developed with three-dimensional imaging software based on intra-operative 3D images provided by the SURGIVISIO Device.
It is indicated for positioning of surgical instruments in vertebrae with a posterior approach in the thoracolumbar region.

The SPX1InstrumentsSPX1 Instrument and Spine CoBot instruments are intended to be used with the SURGIVISIO Device.

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.

510(k) Summary

Submitter Information

Submitter:	ECENTIAL ROBOTICS 2 avenue de Vignate Zone Mayencin II, Parc Equation – Bâtiment 1 38610 Gières France
Contact Person:	Mathilde SAULPIC Quality and Regulatory Affairs Engineer Phone : +33 4 58 00 57 21 Email: mathilde.saulpic@ecential-robotics.com
Date Summary Prepared:	April 4th, 2022

Device Information

Trade or proprietary name:	SURGIVISIO Device
Common or usual name:	Orthopedic Stereotaxic Instrument
Classification Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Regulatory class:	II
Primary product code:	OLO
Legally marketed device to which equivalence is claimed:	- K141941 Stryker SpineMap® 3D Navigation System (available with SpineMask™ tracking device) by Stryker Leibinger GmbH & Co for the free hand navigation feature of the SURGIVISIO Device [Primary], and - K182848 ROSA® ONE Spine application by Medtech S.A.(Zimmer Biomet) for the robotic guidance feature of the SURGIVISIO Device.
Device Description:	The SURGIVISIO Device is a medical device that provides 2D/3D medical imaging and stereotaxic guidance. The subject device offers two stereotaxic guidance features: freehand navigation and robotic guidance. The freehand navigation feature is based on the standard and established technique of navigation systems utilizing optical position determination technology. Like currently marketed optical tracking navigation systems, the operating principle of the freehand navigation feature is based upon the use of a stereoscopic camera emitting infrared light which can determine a 3D position of reflective marker spheres. This allows for real-time tracking of the marker spheres. The system components

	include a stereoscopic camera (SURGIVISIO Camera Pole), a computer platform with monitors (SURGIVISIO Station) and navigation software (3D Spine Universal Workflow software application) and instruments equipped with marker spheres to enable an exact localization in space. The robotic guidance feature utilizes the same principle of optical position determination technology. The system componentss include a stereoscopic camera (SURGIVISIO Camera Pole), a computer platform with monitors (SURGIVISIO Station) and a navigation software (3D Spine Robotic Workflow software application), a robotic arm (CoBot), and instruments equipped with marker spheres to enable an exact localization in space.
Indications 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 through its freehand navigation feature is intended as an intraoperative guidance system to enable open or percutaneous computer-assisted surgery. It is indicated for conditions of the spine in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical bony structure can be identified relative to the intraoperatively generated 3D image of the anatomy provided by the SURGIVISIO Device. It is indicated to precisely position the Navigated Targeting Needle SPX1 during general spinal procedures with a posterior approach. The SURGIVISIO Device through its robotic guidance feature is intended for the positioning of instrument holders or tool guides to be used by surgeons to guide the Spine CoBot instruments during general spinal surgery. Guidance is based on an intra-operative plan developed with three-dimensional imaging software based on intra-operative 3D images provided by the SURGIVISIO Device. It is indicated for positioning of surgical instruments in vertebrae with a posterior approach in the thoracolumbar region. The SPX1instruments and Spine CoBot instruments are intended to be used with the SURGIVISIO Device.

Summary of Technological Characteristics and Comparison to Predicate Device

There are no new technological characteristics in the SURGIVISIO Device as compared to the predicate device. A comparison of the technological characteristics of the SURGIVISIO Device freehand navigation feature to the predicate, the Stryker SpineMap® 3D Navigation System (available with the SpineMask™ tracking device) is provided below:

Characteristics	**Free Hand Navigation Feature of the SURGIVISIO Device** **(Subject device)**	**The Stryker SpineMap® 3D Navigation System with SpineMask™ tracking device (K141941)** **(Predicate device)**
Intended use	The SURGIVISIO Device through its freehand navigation feature is intended as an intraoperative guidance system to enable open or percutaneous computer-assisted surgery. It is indicated for conditions of the spine in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical bony structure can be identified relative to the intraoperatively generated 3D image of the anatomy provided by the SURGIVISIO Device. It is indicated to precisely position the Navigated Targeting Needle SPX1 during general spinal procedures with a posterior approach..	The Stryker SpineMap® 3D Navigation System, when used with a Stryker computer workstation, is intended as a planning and intraoperative guidance system to enable open or percutaneous computer-assisted surgery. The system is indicated for any medical condition in which the use of computer-assisted planning and surgery may be appropriate. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The Stryker SpineMap® 3D Navigation System assists in the precise positioning of instruments for procedures on the spine, including: • Pedicle screw placement Stryker SpineMask™ Tracker Indications for Use The Stryker SpineMask™ Tracker is intended to be used as an accessory to the Stryker SpineMap® 3D Navigation System. It is placed onto the patient's skin dorsal to the spine. • In combination with intraoperative imaging devices, it enables automatic patient registration

		for open or percutaneous computer-assisted surgery. • When used for patient tracking, the Stryker SpineMask™ Tracker supports minimally invasive procedures on the lumbar and thoracic spine
Principle of operation	Uses established computer-assisted orthopedic surgery technologies to navigate targeting needles. Optical localization technology is used to collect intraoperative data and track the relative position of the navigated targeting needle during surgery Uses infrared optical passive sensing technology to collect intraoperative data and track the relative position of the navigated targeting needle during surgery Uses Automatic Intraoperative Registration If the computer unit or camera fails, the user reverts to conventional manual	Uses established computer-assisted orthopedic surgery technologies to navigate targeting needles. Optical localization technology is used to collect intraoperative data and track the relative position of the navigated targeting needle during surgery Uses infrared optical active sensing technology to collect intraoperative data and track the relative position of the navigated targeting needle during surgery Uses Automatic intraoperative registration or anatomical registration or 3D C-Arm registration If the computer unit or camera fails, the user reverts to conventional manual
System accuracy Statement	Mean navigation accuracy of ± 2mm point (tip) displacement and ± 2° angular axis displacement	Mean navigation accuracy of ± 2mm point (tip) displacement and ± 2° angular axis displacement
Dedicated Software	Dedicated freehand spine navigation application software	Dedicated freehand spine navigation application software

There are no new technological characteristics in the SURGIVISIO Device as compared to the predicate device. A comparison of the technological characteristics or the SURGIVISIO Device robotic guidance feature to the predicate, the Medtech S.A.(Zimmer Biomet) ROSA® ONE Spine application is provided below:

Characteristics	**Robotic guidance feature of the Surgivisio Device** **(Spine CoBot Solution)** **(Subject device)**	**ROSA One Spine application (K182848)** **(Predicate device)**
Intended use	The SURGIVISIO Device through its robotic guidance feature is intended for the positioning of instrument holders or tool guides to be used by surgeons to guide the Spine CoBot instruments during general spinal surgery. Guidance is based on an intra-operative plan developed with three-dimensional imaging software based on intra-operative 3D images provided by the SURGIVISIO Device. It is indicated for positioning of surgical instruments in vertebrae with a posterior approach in the thoracolumbar region. The SPX1 instruments and Spine CoBot instruments are intended to be used with the SURGIVISIO Device.	The ROSA one spine application is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by surgeons to guide standard surgical instruments during spine surgeries. Guidance is based on an intraoperative plan developed with three-dimensional imaging software provided that the required fiducial markers and rigid patient anatomy can be identified on 3D CT scans. The device is intended for the placement of pedicle screws in vertebrae with a posterior approach in the thoracolumbar region
General device technology description	Computer-controlled electromechanical arm guiding neurosurgical instruments	Computer-controlled electromechanical arm guiding neurosurgical instruments
Global system functional principal	Stereotactic robotic navigation guidance of spine surgical instrument based on an intra-operative plan developed with three-dimensional imaging software which is based on intraoperative 3D images using an optical system (infrared camera)	Stereotactic robotic navigation guidance of spine surgical instrument based on an intra-operative plan developed with three-dimensional imaging software which is based on intraoperative 3D images using an optical system (infrared camera)
Device accuracy	- Device accuracy: <2 mm - Angular error <2 degrees	- Device accuracy: <2 mm - Angular error <2 degrees
Software	Dedicated Spine application Software	Dedicated Spine application Software

Performance Data

Nonclinical tests:

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

- Design verification tests were performed based on risk management activities and product requirements.
- Software development and testing activites were conducted in accordance with IEC 62304 Medical device software – Life cycle processes and FDA guidance.
- Biocompatibility was evaluated and testing in accordance with ISO 10993 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process..
- Electrical safety and electromagnetic compatibility (EMC) testing were conducted in accordance with IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance and IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.
- The SURGIVISIO Device was validated with intended users in cadaver labs and simulated use testing to ensure the users' needs and intended use requirements were met.

All test requirements were met, no new issues of safety or effectiveness were raised, and substantial equivalence was demonstrated.

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

Conclusions drawn from Performance Data

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR 807, and based upon the information and scientifically valid data provided in this premarket notification, eCential Robotics concludes that the subject device, the SURGIVISIO Device, is as safe and effective and performs as well as the predicate devices, the SpineMap® 3D Navigation System with SpineMask™ tracking device and to the ROSA® ONE Spine application. Substantial equivalence was established in terms of design features, technological characteristics, intended use and performance as compared to the two predicate devices.