July 27, 2023

Ecential Robotics
Elodie Bouillet
Design Process & Regulatory Affaires Manager
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2 avenue de Vignate
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France

Re: K231886
Trade/Device Name: SURGIVISIO Device
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 27, 2023
Received: June 27, 2023

Dear Elodie Bouillet:

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,

Shumaya Ali -S

Shumaya Ali, MPH
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)*
K231886

Device Name
SURGIVISIO Device

Indications for Use *(Describe)*
The SURGIVISIO Device is indicated 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 indicated 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 indicated 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 Instrument and Spine CoBot instruments are designed 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
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Date Summary Prepared: June 27, 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	SURGIVISIO Device by ECENTIAL ROBOTICS:
	- Primary predicate K221028
	- Other predicates
	  ○ K202547
	  ○ K220946
	  ○ K220627

Scope of the submission	The subject device is the SURGIVISIO Device which enables 2D/3D medical imaging and stereotaxic guidance. The 2D/3D medical imaging feature was cleared originally via 510(k) K202547 and via Special 510(k) K220946 and K220627. The stereotaxic guidance including freehand navigation and robotic guidance feature was cleared via 510(k) K221028. The scope of this current submission is limited to the design modification of the Spine CoBot instruments which are used for the Robotic Guidance feature.
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 components 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 indicated 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 indicated 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 indicated 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 intraoperative 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 designed to be used with the SURGIVISIO Device.
Technology comparison	Increase of instruments diameters, modification of the shape of the **CoBot, Drill Guide – Sleeve** teeth, **CoBot, Drill Bit** tip and **CoBot, Drill Bit** connection to power tool. The technology is not impacted by the discussed device change.
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 additives as well as manufacturing processes are not modified following the design change.
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. The accuracy and safety assessment (cadaveric study) were redone in order to ensure that the design modification on the Spine CoBot Instruments do not impact the accuracy and the safety of the Robotic Guidance Feature of the SURGIVISIO Device.
Software Testing	Same as the predicate
Conclusion	Based upon comparison of devices and performance testing results, SURGIVISIO Device is substantially equivalent to the predicate device.

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

Characteristics	**Robotic guidance feature of the SURGIVISIO Device (Subject device)**	**Robotic guidance feature of the SURGIVISIO Device (K221028) (Predicate device)**	**Discussion**
Indications for use	The SURGIVISIO Device through its robotic guidance feature is indicated for the	The SURGIVISIO Device through its robotic guidance feature is intended for the	Similar: word “intended” replaced by “indicated”,

Characteristics	**Robotic guidance feature of the SURGIVISIO Device (Subject device)**	**Robotic guidance feature of the SURGIVISIO Device (K221028) (Predicate device)**	**Discussion**
	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 designed to be used with the SURGIVISIO Device.	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.	"intended" replaced by "designed" while the statement of indications for use is the same. Safety and performance of the system are not questioned.
Anatomical site	The SURGIVISIO Device through its robotic guidance feature is indicated for positioning of surgical instruments in vertebrae with a posterior approach **in the thoracolumbar region.**	The SURGIVISIO Device through its robotic guidance feature is indicated for positioning of surgical instruments in vertebrae with a posterior approach **in the thoracolumbar region.**	Identical
Patient population	The SURGIVISIO Device through its robotic guidance feature is indicated for a population with medical conditions requiring the treatment of diseases with the placement of spinal instruments and for which the use of stereotactic surgery may be considered to be appropriate and after consideration of the compatibility of patient spinal anatomy with dimensions of the Spine CoBot Instruments and dimensions of virtual implants proposed by the 3D Spine Robotics workflow surgical plan.	The SURGIVISIO Device through its robotic guidance feature is indicated for a population with medical conditions requiring the treatment of diseases with the placement of spinal instruments and for which the use of stereotactic surgery may be considered to be appropriate and after consideration of the compatibility of patient spinal anatomy with dimensions of the Spine CoBot Instruments and dimensions of virtual implants proposed by the 3D Spine Robotics workflow surgical plan.	Identical
TECHNOLOGICAL CHARACTERISTICS			

Characteristics	Robotic guidance feature of the SURGIVISIO Device (Subject device)	Robotic guidance feature of the SURGIVISIO Device (K221028) (Predicate device)	Discussion
General device technology description	Computer-controlled electromechanical arm guiding neurosurgical instruments	Computer-controlled electromechanical arm guiding neurosurgical instruments	Identical
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)	Identical
Surgical work Flow	1. Patient and device installation 2. Intraoperative image acquisition 3. Registration 4. Intraoperative planning 5. Spine instrument holder positioning 6. Instrument guidance 7. Screw implantation	1. Patient and device installation 2. Intraoperative image acquisition 3. Registration 4. Intraoperative planning 5. Spine instrument holder positioning 6. Instrument guidance 7. Screw implantation	Identical
Graphical User Interface	System-specific GUI	System-specific GUI	Identical
Surgeon control	- The surgeon controls the motion of the robotic arm from one screw position to the next by pressing the foot pedal and the manual button. The surgeon carries out the final positioning through the instrument guide with a traditional surgical instrument.	- The surgeon controls the motion of the robotic arm from one screw position to the next by pressing the foot pedal and the manual button. The surgeon carries out the final positioning through the instrument guide with a traditional surgical instrument.	Identical
Device accuracy	- Device accuracy: <2 mm - Angular error: <2 degrees	- Device accuracy: <2 mm - Angular error: <2 degrees	Identical
SYSTEM COMPONENTS DESIGN			

Characteristics	Robotic guidance feature of the SURGIVISIO Device (Subject device)	Robotic guidance feature of the SURGIVISIO Device (K221028) (Predicate device)	Discussion
Overall Device Design	SURGIVISIO Device Robotic guidance feature is composed of the following main components: - Stations - Dedicated software - Robotic arm - Camera pole - Dedicated instruments	SURGIVISIO Device Robotic guidance feature is composed of the following main components: - Stations - Dedicated software - Robotic arm - Camera pole - Dedicated instruments	Identical
Stations	- Base station (SURGIVISIO Station): two display monitors, computer unit, power supply. - Robotic Station (CoBot): robotic arm, control box for the robotic arm, power supply, foot pedal	- Base station (SURGIVISIO Station): two display monitors, computer unit, power supply. - Robotic Station (CoBot): robotic arm, control box for the robotic arm, power supply, foot pedal	Identical
Software	- Dedicated spine application software	- Dedicated spine application software	Identical
Robotic arm	- Guides spine instruments during general spine surgery - Instruments are mounted onto the robot arm's flange - Uses seven degrees of freedom architecture to guide instruments - Uses foot pedal and/or manual buttons for automatic alignment and cooperative mode - Has light indicators that reflect the status of the robotic guidance	- Guides spine instruments during general spine surgery - Instruments are mounted onto the robot arm's flange - Uses seven degrees of freedom architecture to guide instruments - Uses foot pedal and/or manual buttons for automatic alignment and cooperative mode - Has light indicators that reflect the status of the robotic guidance	Identical
Optical localizer	- An infrared camera detects reflective markers to track the position of the	- An infrared camera detects reflective markers to track the position of the	Identical

Characteristics	Robotic guidance feature of the SURGIVISIO Device (Subject device)	Robotic guidance feature of the SURGIVISIO Device (K221028) (Predicate device)	Discussion
	robotic arm and instruments	robotic arm and instruments	
Instruments	- Robotic instruments (Spine CoBot Instruments: CoBot, Tool Holder; Robotic, Tool holder - Tracker; CoBot, Drill Guide – Cortical Tip; CoBot, Drill Guide – Sleeve; CoBot, Drill Bit; 3.5 mm Hex Head Screwdriver; Fixation Screws, CoBot Spine Instruments Tray) - Navigation instruments (SPX1 instruments)	- Robotic instruments (Spine CoBot Instruments: CoBot, Tool Holder; Robotic, Tool holder - Tracker; CoBot, Drill Guide – Cortical Tip; CoBot, Drill Guide – Sleeve; CoBot, Drill Bit; 3.5 mm Hex Head Screwdriver; Fixation Screws, CoBot Spine Instruments Tray) - Navigation instruments (SPX1 instruments)	Similar: the design of CoBot, Tool Holder, CoBot, Drill Bit, CoBot, Drill Guide – Sleeve, and CoBot, Drill Guide – Cortical Tip is modified (scope of this submission) however the use of those instruments is unchanged and the performance and the safety of the system is not impacted (see section 11 – Design Control Activities Summary).

Performance Data

For further information about testing, standards, acceptance criteria and results, please refer to section 11 Design Control Activities Summary.

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

- The Sterilization validation part of the reprocessing validation of the Spine CoBot Instruments has been performed.
- A cadaveric study has been performed to assess:
  - The accuracy of the robotic guidance feature
  - The safety of the robotic guidance feature

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

Conclusions drawn from Performance Data

The SURGIVISIO Device 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/K220946/K220627/K221028) and that the SURGIVISIO Device does not raise different questions of safety and effectiveness when compared to this predicate.