Surgivisio
% Elodie Bouillet
Quality and Regulatory Affairs Engineer
Zone Mayencin II, Parc Equation - Bâtiment 1
2 Avenue de Vignate
Gières, 38610
FRANCE

March 26, 2021

Re: K202547
Trade/Device Name: Surgivisio system
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: February 23, 2021
Received: March 1, 2021

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,

For

Thalia T. Mills, Ph.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202547

Device Name
Surgivisio system

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.

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510(k) Summary
K202547

Submitter Information

Submitter: Surgivisio
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France

Contact Person: Vincent Leré
Quality/Regulatory Affairs Director
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Date Summary Prepared: July 31st, 2020

Device Information

Trade or proprietary name: Surgivisio system

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: K042793 - Arcadis Orbic (available with options 3D and 3D navigation interface) - Manufacturer: Siemens Medical Solutions, Inc

Device Description: The Surgivisio system 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 ends 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.

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.

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

The Surgivisio system is substantially equivalent to the Arcadis Orbic (available with options 3D and 3D navigation interface) - K042793

Devices	**Surgivisio system**	**The Arcadis Orbic with options 3D and 3D navigation interface (K042793)**
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 Arcadis Orbic is a mobile X-ray system designed to provide fluoroscopic and digital spot-film imaging of the patient during surgical and interventional procedures. Clinical application may include, but are not limited to, cholangiography, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The Arcadis Orbic 3D option provides 3D imaging and is intended to be used whenever the physician benefits form intraoperatively-generated 3D information of high contrast objects and anatomical structures.

Device	Surgivisio system	The Arcadis Orbic with options 3D and 3D navigation interface (K042793)
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 40cm Horizontal: Up to 20cm Orbital: 190° Angulation: 190°
Movement control	Motor-driven	Manual Motor-driven
kV Range	40 – 120 kV	40-110 kV
mA Range	1 – 120 mA	0.2 – 15.2 mA, pulsed up to 23 mA mAs up to 150
Pulse frequency	1 – 12.5 fps	Up to 15 fps
Detector technology	Flat panel, 287mm x 265mm	X-ray Image intensifier Ø23cm
Image Matrix Size	1560x1440 pixels 780x720 pixels	1024x1024 pixels
X-ray tube technology	Rotating anode 0.3 – 0.8 focal spot	Stationary anode 0.6 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°	[120° - 190°]
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	Cubic volume: 11 x 11 x 11 cm
Monitor cart/Workstation	Yes	Yes
Screen displays	2 Monitors 22” tactile Screen Displays	2 Monitors 19” Screen Displays
Image output format	DICOM	DICOM
LAN network connection	Yes	Yes
Computer Aided Surgery (CAS) interface	Yes, integrated	Yes, provides the 3D navigation interface that enables interoperability with navigation systems

Performance Data

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

- IEC 60601-1 (Edition 3.1): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 (Edition 4.0): Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-3 (Edition 2.1): Medical electrical equipment – Part 1-3 : General requirements for basic safety and essential performance – Collateral Standard : Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-43 (Edition 2.1): Medical electrical equipment – Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures
- IEC 60601-2-54 (Edition 1.1): Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy [Including: Amendment 2 (2018)]
- 2D Image Quality Assessment of the Surgivisio system provides a quantitative image quality assessment of subject device in comparison to the predicate device
- Basic CBCT bench testing using phantoms and based on standard IEC 60601-2-44 (Edition 3.2) Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography, to demonstrate the effectiveness and safety of the subject device
- Concurrence study using a distortion phantom to demonstrate the ability of the subject device to provide 3D images equivalent to those of the predicate device
- Quality characterization of the iterative 3D reconstruction algorithm to demonstrate the effectiveness of the 3D imaging feature
- 3D image quality assessment with breathing simulation to demonstrate the effectiveness of the 3D imaging feature
- Sample clinical images evaluated by a qualified expert to support the intended use of the 2D and 3D imaging features
- Comparison of radiation doses associated with clinical image data provided by the subject device to literature
- 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 system 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 Arcadis Orbic system (K042793) and that the Surgivisio system does not raise different questions of safety and effectiveness when compared to this predicate.