January 6, 2025

Omega Medical Imaging, LLC
℅ Matthew Anderson
Director of RA/QA
3400 St. Johns Parkway, Suite 1020
SANFORD, FL 32771

Re: K242488
Trade/Device Name: Soteria E-View
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: JAA, OWB
Dated: August 15, 2024
Received: December 11, 2024

Dear Matthew Anderson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242488

Device Name

Soteria E-View

Indications for Use *(Describe)*

The System is intended for use in Radiographic / Fluoroscopic applications including general radiographic / fluoroscopic diagnostic, and interventional X-Ray imaging for General and Pediatric Populations.

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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Traditional 510(k) SUMMARY K242488

Company Name:	Omega Medical Imaging, LLC
Address:	3400 St. Johns Parkway, Suite 1020, Sanford, Fl 32771
Telephone No:	407-323-9400
Registration No:	1052701
Contact person:	Matthew Anderson, Director RA/QA
Date Prepared:	06/04/2024
Device (trade) name:	Soteria E-View
Common/usual name:	Fluoroscopic/Radiographic X-ray system
Classification Name:	Image-intensified Fluoroscopic X-ray system
Classification Panel:	Radiology
CFR section:	892.1650
Device Class:	Class II
Primary Product code:	JAA
Secondary product code:	OWB

Predicate Device K212336

Company Name:	Omega Medical Imaging, LLC
Address:	3400 St. Johns Parkway, Suite 1020, Sanford, Fl 32771
Telephone No:	407-323-9400
Registration No:	1052701
Contact person:	John Newman
Date Prepared:	08/19/2021
Device (trade) name:	Soteria.AI
Common/usual name:	Fluoroscopic/Radiographic X-ray system
Classification Name:	Image-intensified Fluoroscopic X-ray system
Classification Panel:	Radiology
CFR section:	892.1650
Device Class:	Class II
Primary Product code:	JAA
Secondary Product code:	OWB

Indications for use:

The System is intended for use in Radiographic/fluoroscopic applications including general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging for General and Pediatric Populations.

Device Description:

The Soteria E-View system is classified as an interventional fluoroscopic X-ray system. The fundamental performance characteristics of the Soteria E-View interventional fluoroscopic X-ray system consists of:

- The patient table and C- arm with X-ray source on one side and the flat panel detector on the opposite side. The C-arm can be angulated in both planes, and the flat panel detector can be lifted vertically. The tabletop can be shifted from side to side and move forward/backward by an operator.
- Real-time image visualization of patient anatomy during procedures.
- Imaging techniques and tools to assist interventional procedures.
- Post-processing functions after interventional procedures.
- Storage of reference/control images for patient records.
- Compatibility to images of other modalities via DICOM.
- Built-in radiation safety controls-with the already FDA cleared CA-100S /FluoroShield (K182834).

This array of functions provides the physician with the imaging information required to achieve minimally invasive interventional procedures.

The Soteria E-View system is available as a Model GI-100 configuration. It is similar to the currently marketed predicate Soteria.AI consisting of an X-ray generator, image processor, collimator, X-ray Tube, Positioner, and patient table with CA-100S / FluoroShield Accessory, (K212336).

Patient Population:

General and Pediatric Population, special concerns must be taken for pediatric use.

Based on the information provided above, the Soteria E-View system is considered substantially equivalent to the current marketed predicate device Soteria. AI (K212336). Both share the same Indications for use.

(Note: Cardiac and Vascular application removed from the Soteria E-View indications for use)

Technological characteristics and Summary of Critical Improvements:

The Soteria E-View system has similar technological characteristics compared to the predicate device with some changes to it. Below is a summary of the changes between the new Soteria E-View system and the predicate device. FluoroShield was integrated with the Varex Azure 3131Z CXP Flat Panel Detector.

- Replace 80KV high voltage generator with GI Epsilon Generator (E-view), X-ray generator is certified separately.
- The positioner changed from L/C to I/C configuration.
- Updated 12 and 24V Power supplies in electronics cabinet with newer more available UL compliant units.
- Added fluoro, spot and save buttons to positioner controls.
- Upgrade actuators to support Linak instead of SKF.
- Shorter GI patient table that supports an 800-pound patient, as this is a more suitable table configuration for Gastrointestinal interventional procedures.
- The Nyquist image processor is now configured with a Varex 3131x CXP detector, as Indium Gallium Zinc Oxide technology has a high quantum efficiency and lower dose than traditional CMOS detectors.
- Replaced Powertronix IsoStation Isolation Transformer and Ametek UPS combination with a single Astrodyne TDI UL certified PowerBridge which combines the isolation transformer and UPS into a single unit.

The difference between the Soteria E-View system and the predicate device does not raise any new safety or effectiveness. Based on the information provided in this 510K submission, Soteria E-View is considered substantially equivalent to the current marketed predicate Soteria. AI (K212336)

Clinically:

- **Legacy E-view (K062647)** and **Soteria E-view (GI-100)** are virtually identical in terms of the Positioner and Table movements and capabilities.
- Same Tube
- Same Generator
- Same Table Size

Summary of Non- Clinical Performance

Non-clinical and Sample clinical images were used to validate image performance. This testing has been performed on the Soteria E-View system to demonstrate substantial equivalence to the predicate device.

1. IEC 62304 Medical device software – Software life cycle processes. FDA/CDRH recognition number 13-79.
2. ISO 14971 Medical devices – Application of risk management to medical devices
3. IEC 60601-2-54 - Particular requirements for basic safety and essential performance of X-ray Safety.

4. IEC60601-2-43 - Particular requirements for the basic safety and essential performance of x-ray equipment for interventional procedures.
5. Guidance for Industry and FDA Staff - Guidance for the Content of premarket Submissions for Device Software function. June 2023
6. "Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", July 28, 2014 (document number 1766).
7. Guidance for industry and FDA staff – Electronic Submission Template for Medical Device 510(k) submissions. Oct. 2023

Software verification testing of the functional and non-functional requirements, as well as performance, reliability, and safety, have been performed to verify that all conditions of System requirements Specifications, as well as the safety risk control measures from the detailed Risk management and the privacy and security requirements, have been implemented. Results demonstrated that the executed verification test was passed.

Non- clinical and Sample clinical images were used for validation testing of the Soteria E-View system to demonstrate conformance to the intended use, claims, user, and service needs, effectively satisfying measures and instruction for use.

The Soteria E-View was demonstrated with the following attributes:

- Indication for use.
- Technological characteristics.
- Non-clinical and Sample clinical image performance testing.
- Safety and effectiveness.

Substantial equivalence Conclusion:

The Soteria E-View system is substantially equivalent to the currently marketed predicate device Soteria.AI regarding indications for use, technological characteristics, safety, and effectiveness.

Therefore, Soteria E-View is as safe and effective as its predicate device and does not raise any new safety and effectiveness concerns.

Comparison with Predicate Devices:

Indications for use comparison:		
510(k) Number and Device Name	K212336 (Predicate Device) Soteria.AI, Model AI-100	K242488 (This Submission) Soteria E-View, Model GI-100
Intended Use	The Omega Medical Imaging, LLC AI-100, Soteria.AI (SSXI) systems with FluoroShield / CA-100S device to provide an automated Region of interest that reduces exposure to the patient and operator. The System is intended for use in Radiographic/fluoroscopic applications, including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging for General and Pediatric Populations.	The Omega Medical Imaging, LLC GI-100, Soteria E-View (SSXI) systems with FluoroShield / CA-100S device to provide an automated Region of interest that reduces exposure to the patient and operator. The System is intended for use in Radiographic/fluoroscopic applications, including gastrointestinal, ERCP, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging for General and Pediatric Populations.
Classification Name:	Image-intensified Fluoroscopic X-ray system	Image-intensified Fluoroscopic X-ray system
CFR Regulation #:	892.1650	892.1650
Device Class	Class II	Class II
Classification Product Code:	JAA, OWB	JAA, OWB

PRODUCT OVERVIEW

Substantial Equivalence:

1. Flat Panel Detectors		
	510(k) Cleared (Predicate Device) K212336	**This Submission Soteria E-View**
Detector Name:	Teledyne Dalsa Xineos-3030HS	Varex Azure 3131Z CXP Detector
1.1 Receptor Type	CMOS	IGZO (indium gallium zinc oxide)
1.2 Conversion Screen	Cesium Iodide	Cesium Iodide
1.3 Pixel Area – Active	29.6 cm x 29.6 cm	30.7 cm x 30.7 cm
1.4 Pixel Matrix – Active	1952 x 1952	2048 x 2048
1.5 Pixel Pitch	151.8 µm	150 µm
1.6 Limiting Resolution	3.15 lp/mm	3.3 lp/mm
1.7 MTF, X-ray	58% @ (1.0 lp/mm at RQA5 1x1)	60% @ (1.0 lp/mm)
1.8 Energy Range	40 - 125 kV	40-125 kV
1.9 Fill Factor	83%	66%
1.10 Dynamic Range	77dB	65 dB
1.9 A/D Conversion	16-bits	16-bits

2. Acquisition is the same for all Flat Panel Detectors		
2.1 Modes	Pulsed Fluoro, Spot, Cine, Roadmaping (Subtration Fluoroscopy) and DSA	Pulsed Fluoro and Spot
2.2 Pulsed Fluoro Rates	3.75, 7.5, and 14 pps	3, 6, and 12.5 pps
2.3 Spot Rates	1, 2, 3,4, and 6 fps	1, 2, 3,4, and 6 fps
2.4 Cine Rates	7.5, 15, and 30 fps	No Cine
2.5 Polarity	Positive & Negative	Positive & Negative
2.6 Edge Enhancement	5 levels	5 levels
2.7 Noise Reduction	5 levels	5 levels
2.8 Last Image Hold	Yes	Yes
2.9 Fluoro Loops	Yes	Yes
2.10 Horizontal & Vertical Flip	Yes	Yes
3. Acquisition Workstation		
3.1 Workstation Model	Nyquist	Nyquist
3.2 Monitor, size	2 x 21.3 inch, Medical Grade Color, High Contrast	2 x 21.3 inch, Medical Grade Color, High Contrast
3.3 Grey Levels	10-bit, Display Port	10-bit, Display Port
3.4 Review (Fluoro Loops/Cine)	Forward, Reverse, Pause, and Play	Forward, Reverse, Pause, and Play
3.5 Window/Level Adjust	Yes	Yes
3.6 Annotation	Yes	Yes
3.7 Image Invert	Yes	Yes
3.8 Horizontal & Vertical Flip	Yes	Yes
3.9 Zoom & Roam	Yes (2x)	Yes (2x)
3.10 Image Storage	Minimum: 225,000 images	Minimum: 225,000 images
3.11 Networking Capabilities	Gigabit ethernet 10/100/1000	Gigabit ethernet 10/100/1000
3.12 DICOM Worklist Query	Yes	Yes

3.13 DICOM Storage	Yes	Yes
3.14 DICOM Storage to DVD/CD	With Embedded Viewer	With Embedded Viewer
4. Reference Monitor Identifiers [Review Station]		
4.1 Patient Name	Yes	Yes
4.2 Patient I.D.	Yes	Yes
4.3 Date	No	No
4.4 Time	No	No
4.5 Window/Level	No	No
4.6 Hospital Name	No	No
4.7 Physician Name	Yes	Yes
4.8 Study I.D.	Yes	Yes
4.9 Series/Image	Yes	Yes
4.10 Acquisition Mode	Yes	Yes
4.11 Image Orientation	Yes	Yes
4.12 Radiation	No	No
I4.13 Image I.D.	Yes	Yes
5. Live Monitor Identifiers [Image Area]		
5.1 Patient Name	Yes	Yes
5.2 Patient I.D.	Yes	Yes
5.3 Date	Yes	Yes
5.4 Time	Yes	Yes
5.5 Window/Level	No	No
5.6 Hospital Name	Yes	Yes
5.7 Physician Name	No	No
5.8 Study I.D.	Yes	Yes
5.9 Series/Image	Only Image Number	Only Image Number
5.10 Image Orientation	Yes	Yes
5.11 Radiation Symbol	Radiation symbol during Live	Radiation symbol during Live

5.12 Image I.D.	e.g., FL LIH, FL Loops, Spot Replay, or Cine Replay	e.g., FL LIH, FL Loops, Spot Replay, or Cine Replay
5.13 Detector Status	Ready/Not Ready	Ready/Not Ready
5.14 Magnification Mode	Normal, MAG 1, MAG 2	Normal, MAG 1, MAG 2
5.15 Loop Replay	Play, Forward, Reverse, Play, & Pause	Play, Forward, Reverse, Play, & Pause
GUI [Graphic User Interface on Reference Monitor]		
Patient/Exam Entry		
5.16 Directory	Opens 'Patient Directory' screen	Opens 'Patient Directory' screen
5.17 New	Opens 'Patient Data Entry' screen	Opens 'Patient Data Entry' screen
5.18 Close	Closes active patient	Closes active patient
Acquisition		
5.19 NR Hi / NR Lo	Selects Noise Reduction Level	Selects Noise Reduction Level
5.20 L -> R	Live to Reference (monitor) transfer	Live to Reference (monitor) transfer
5.21 Fluoro Pulse Rates:	Pulse Rates: [14 f/s default, 7.5, & 3.75 f/s]	Pulse Rates: [12.5 f/s default, 6, & 3 f/s]
Note: Image Orientation available for Acquisition Mode [from Review]		
Review		
5.22 Edge [enhancement]	Increments from 1 - 5	Increments from 1 - 5
5.23 Win./Lev.	Window/Level adjustment	Window/Level adjustment
5.24 Split	Invokes 4 on 1 image display, No	Invokes 4 on 1 image display, No
5.25 Reference – Live	Toggles image between the Reference and Live monitors	Toggles image between the Reference and Live monitors
5.26 Zoom	Up to 2X zoom with panning	Up to 2X zoom with panning
5.27 Polarity	Video white on black or black on white	Video white on black or black on white
5.28 Collimate	Invokes electronic shutters	Invokes electronic shutters

5.29 R [image orientation]	Toggles thru 1 of 4 positions	Toggles thru 1 of 4 positions
Additional Functions		
5.30 Send	Opens 'DICOM server node selection'	Opens 'DICOM server node selection'
5.31 Print	Sends image to a Windows® compatible printer (No)	Sends image to a Windows® compatible printer (No)
5.32 Save	Saves current image to Hard Drive	Saves current image to Hard Drive
5.33Text	Invokes the Annotation and Measurement function	Invokes the Annotation and Measurement function
C-Arm & Operator Controls		
C-ARM Specifications:	**510(k) Cleared (Predicate Device) K212336**	**This Submission Soteria E-View.AI**
C-Angulation	Head ± 110° ± 2°, Side ± 45° ± 2°,	± 90°, ± 2°
C-Roll	Head ± 45° ± 2°, Side ± 90° ± 2°,	+ 90°, ± 2°, -75°, ± 2°
Iso-Rotation	± 90°, ± 2°	No
Collimator - Longitude	Opens to full field, closes fully	Opens to full field, closes fully
Collimator – Latitude	Opens to full field, closes fully	Opens to full field, closes fully
Cardio Filter – Open Close	Opens to full field, closes fully (vascular), closes to mid field (lung)	No Filter
Cardio Filter – Rotate	Rotates cardio filter(s) 360°	No Filter
Variable SID	13", ± 1"	13", ± 1"
Operator Controls		
Fluoro Enable	Enables/disables Fluoro function	Enables/disables Fluoro function
Fluoro Timer Reset	Resets 5-minute alarm on high voltage generator	Resets 5-minute alarm on high voltage generator
Emergency Stop	Disables motion actuators and high voltage generator	Disables motion actuators and high voltage generator
Magnification mode	Selects field sizes: Normal, Mag 1, and Mag 2	Selects field sizes: Normal, Mag 1, and Mag 2

Controls select	Requests active control is 2 controllers are installed	Requests active control is 2 controllers are installed
5th Axis Rotate	± 90°, ± 2°	No
Cardio filter select	Lung or vascular	No
DAP meter reset	Resets DAP meter outputs to 0	Resets DAP meter outputs to 0
Pediatric Filter Select	Selects none, 0.1, 0.2, or 0.3 mm Cu filters	No
Parking Control	Controls parking actuator	No
Fluoro	Enables X-ray fluoro	Enables X-ray fluoro
Fluoro loops	Enables X-ray fluoro loops	Enables X-ray fluoro loops
Cine	Enables X-ray cine mode	No
Miscellaneous Functions:		
System Digital Display	Miscellaneous System Status	Miscellaneous System Status
Collision Sensing on FPD	Bump stop.	Bump stop.
Collimator Functions:		
Collimator: Maximum Size and Tracking	Yes	Yes
Collimator: Minimum Size	Yes	Yes
X-Ray Specifications		
Half Value Layer	Minimum value = 3.6 mm Al equiv. @ 100 kV Maximum value = 4.0 mm Al Equiv. @ 100 kV	Minimum value = 3.6 mm Al equiv. @ 100 kV Maximum value = 4.0 mm Al Equiv. @ 100 kV
Tabletop Aluminum Equivalence	Rejection Limit: 2.00 mm Al max.	Rejection Limit: 1.6 mm Al max.
Dose Calibration: Maximum Input Dose Rate	80 to 85 mGy/minute	80 to 85 mGy/minute
Dose Calibration: Max Input Dose Rate	2.3 to 2.9 µR/frame	2.3 to 2.9 µR/frame
Dose Calibration: Flat Panel Input Dose rate	0.8 µGy/sec.	0.8 µGy/sec.
Generator Function: Pulsed Fluoro Function	Yes	Yes
Generator Function: ABC Function	Yes	Yes
Image Quality: Resolution	Up to 3.15 lp/mm	Up to 3.15 lp/mm
Last Image Hold	Yes	Yes
Patient Table Specifications:		

Table Specifications:	510(k) Cleared (Predicate Device) K212336	This Submission Soteria E-View
Table Lock Manual Disable Controls	Unlocks table rotate, latitude and longitude.	No
Table Trendelenburg	± 15°, ± 1°	± 12°, ± 1°
Table height	33" to 45"	Same
Table cradle (LAO/RAO)	± 15°, ± 1°	± 12°, ± 1°
Table Rotation	0° to 90°	No
X-RAY TUBE Specifications:		
X-RAY Tube Specifications:	**510(k) Cleared (Predicate Device) K212336**	**This Submission Soteria E-View**
Tube Model:	G-2090	G-1092
Heat Exchanger	HE-280	HE-100
Focal Spot sizes	0.6 - 1.0 mm	0.6 – 1.2mm
Heat Unit rating	2.0 MHU	1.0 MHU
Housing Model:	B-240H	B-160
High Voltage Generator		
H.V. Generator Specifications:	**510(k) Cleared (Predicate Device) K212336**	**This Submission Soteria E-View**
Model:	EMD Technologies EPS High Voltage Generator series	EMD Technologies EPS High Voltage Generator series
Mains Input Power:	480 Vac +/- 10% 50/60 Hz (3 phases)	480 Vac +/- 10% 50/60 Hz (3 phases)
kV range:	40 kV - 125 kV	40 kV - 125 kV
mA range:	Min: 5mA to Max: 1000mA	Min: 5mA to Max: 1000mA
CA-100S / FluoroShield		
ROI: 'ON' ,'OFF', 'ERROR', or 'BYPASS'	Yes	Yes
'AUTO' or 'MANUAL' ROI	Yes	Yes
'HIGH' or 'LOW' reduction	Yes	Yes

Safety information:

- The Omega Soteria E-View systems comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega Soteria E-View systems comply with the international safety standards EN 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-4, IEC 60601-1-6, IEC 60601-2-54, IEC 60601-2-43, EN ISO 15223-1, and EN ISO 14971.
- The Omega Soteria E-View systems comply with UL 60601-1 and CAN/USA C22.2 No.601.1-M90.
- The device is designed and manufactured under the Quality System Regulations outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with applicable parts of the IEC60601-1 standards and its collateral standards. All Federal Diagnostic Equipment Standard requirements, as outlined in 21 CFR § 1020, that apply to this device will be met and reported in this initial report.
- This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard].

Safety is assured through a risk management process, and manufacturing complies with the Quality System Regulations.

Referenced Guidance Documents:

- Guidance for this submission of 510(k) **for Indications of use as provided in Pediatric Information for X-ray Imaging Device Premarket Notifications** (Document issued on November 28, 2017) Guidance for Industry and Food and Drug Administration Staff.
- Guidance for the Content of Premarket Submissions for **Management of Cybersecurity in Medical Devices**. (Document issued September 2023)
- Guidance for the Content of Premarket Submissions for **Software Contained in Medical Devices** (Document issued June 2023)
- Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically powered Medical Devices.** (Document issued June 2022)
- Guidance for this submission of 510(k) for **(SSXID) Solid State X-ray Imaging Devices** issued on: September 1, 2016, was used to establish substantial equivalence.
- Guidance for industry and FDA Staff - **User Fees and Refunds for Premarket Notification Submissions 510(k)s,** (Document issued October 2022)
- Guidance for industry and FDA Staff - **Refuse to Accept Policy for 510(k)** (Document issued April 2022)
- Guidance for industry and FDA Staff -**Format for Traditional and Abbreviated 510(k)s** (Document issued on September 2019)
- Guidance for industry and FDA Staff - **Deciding when to submit a 510(k) for a change to an existing device.** (Document issued on October 25, 2017)
- Guidance for industry and FDA Staff - **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** (Document Issued on July 28, 2014)
- Guidance for industry and FDA Staff - **Guidance for Off-The-Shelf Software Use in Medical Devices** (Document issued August 2023)
- Guidance for industry and FDA Staff - **Guidance for the Content of Premarket Submission for Software in Medical Devices.** (Document issued June 2023)
- Guidance for industry and Food and Drug Administration Staff - **Policy Clarification for Certain Fluoroscopic Equipment Requirements** (Document issued on May 8, 2019)
- Guidance for Industry and FDA Staff - **Medical X-Ray Imaging Devices Conformance with IEC Standards.** (Document issued February 2023)
- Guidance for Industry and FDA Staff - **Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment.** (Document issued on December 17, 2018)
- Guidance for Industry and FDA Administration Staff - **Pediatric Information for X-ray Imaging Device Premarket Notifications** (Document issued on November 28, 2017)