Omega Medical Imaging, LLC
John Newman
Regulatory Specialist
3400 St. Johns Parkway, Suite 1020
Sanford, Florida 32771

December 14, 2021

Re: K212336
Trade/Device Name: Soteria.AI
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, OWB

Dear John Newman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 17, 2021. Specifically, FDA is updating this SE Letter to include the updated IFU statement as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Thalia Mills, OHT7: Office of In Vitro Diagnostics and Radiological Health, **Thalia.Mills@fda.hhs.gov.**

Sincerely,

Michael D. O'Hara

For

Thalia Mills, Ph.D.
Division 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

November 17, 2021

Omega Medical Imaging, LLC
% Mr. John Newman
Regulatory Specialist
3400 St. Johns Parkway, Suite 1020
SANFORD FL 32771

Re: K212336
Trade/Device Name: Soteria.AI
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, OWB
Dated: August 17, 2021
Received: August 19, 2021

Dear Mr. Newman:

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 M. Burk -S Digitally signed by Laurel M. Burk -S Date: 2021.11.17 12:15:41 -05'00' , 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212336

Device Name
Soteria.AI

Indications for Use *(Describe)*
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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) SUMMARY

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 (Regulatory Affairs Specialist)
Date Prepared:	07/16/2021
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
Performance Standard:	This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products (21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard)

Predicate Device K182834

Company Name:	Omega Medical Imaging, LLC
Address:	675 Hickman Circle, Sanford, Florida 32771
Telephone No:	407-323-9400
Registration No:	1052701
Contact person:	John Newman
Date Prepared:	02/13/2019
Device (trade) name:	CS-series-FP with Optional CA-100S ROI Accessory
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 cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging for General and Pediatric Populations.

Device description:

The **Soteria.AI** system is classified as an interventional fluoroscopic X-ray system. The fundamental performance characteristics of the **Soteria.AI** 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, lifted vertically, shifted to the side, and moved 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 the imaging information required to achieve minimally invasive interventional procedures.

The Soteria.AI system is available as a Model AI-100 configuration. It is similar to the currently marketed predicate consisting of an X-ray generator, Image processor, collimator, x-ray Tube, Positioner, and patient table with CA-100S / FluoroShield Accessory, (K182834).

Additionally, Soteria.AI can be equipped with an optional X-ray VVA (Vessel and Ventricular Analysis) image analysis (FDA-Cleared) software, (K112807).

Patient Population:

General and Pediatric Population, special concerns must be taken for pediatric use. (See Operator Manual for specific instructions)

Based on the information provided above, the Soteria.AI system is considered substantially equivalent to the current marketed predicate device CS- series-FP with the Optional CA-100S / FluoroShield (K182834). Both share the same Indications for use.

Technological characteristics and Summary of Critical Improvements

The Soteria.AI system has similar technological characteristics compared to the predicate device with some improvements to it. Below is a summary of the critical improvements between the new Soteria.AI system and the predicate device. FluoroShield was integrated with the Teledyne Zineos 3030HS Flat Panel Detector and the Nyquist.IQ Image Processor, Verification and Validation is included in this submission.

- Modified C-arm with the additional rotational axis (Fifth Axis).
- New motion control software for patient and X-ray beam positioning, giving an improved roll scan time.
- Improved collimator, new tube model with higher heat capacity.
- More consistent collision prevention.
- New Image Processor called Nyquist. IQ
- Integration of a New Flat Panel Detector (Teledyne Xineos 3030HS CMOS x-ray detector previously cleared K192182) with the already FDA-cleared CA-100S / FluoroShield (K182834).
- FluoroShield software was revised to accommodate Frame Rate and resolution requirements for the Teledyne Xineos 3030HS CMOS FPD and Nyquist Image Processor.
- Operator TouchPad interface.
- Operator programable presets for the position of the C-arm and Table.

The difference between the Soteria.AI system and the predicate device does not raise any new safety or effectiveness. Based on the information provided in this 510K submission, Soteria.AI is considered substantially equivalent to the current marketed predicate CS-series-FP with the Optional CA-100S / FluoroShield in terms of fundamental technology.

Summary of Non- Clinical Performance

Non-clinical performance testing has been performed on the Soteria.AI system and demonstrated compliance with the following International and FDA approved consensus standard and FDA guidance documents:

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 the basic safety and essential performance of X-ray Safety.
4. Guidance for Industry and FDA Staff - Guidance for the Content of premarket Submissions for Software Contained in Medical Devices, May 11, 2005 (document number 337).
5. “Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”, July 28, 2014 (document number 1766).

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 executed verification test was passed.

Non- clinical validation testing has been performed to validate that the Soteria.AI system conforms to the intended use, claims, user, and service needs, effectively satisfying measures and instruction for use.

The Soteria.AI did not require clinical study data since substantial equivalence to the currently marketed predicate device *Omega CS-series-FP* was demonstrated with the following attributes:

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

Substantial equivalence Conclusion:

The Soteria.AI system is substantially equivalent to the currently marketed predicate device CS- series- with the Optional CA-100S (ROI Assembly) regarding indications for use, technological characteristics, safety, and effectiveness.

The Soteria.AI system is within the controls and predetermined specifications. Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in these 510(k) premarket notifications. These tests demonstrate that the Soteria.AI system complies with the user need requirements and the requirements specified in the FDA-recognized consensus standards and guidance documents.

Therefore, Soteria.AI 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	K182834 (Predicate Device) CS-series-FP with optional CA-100S	(This Submission) Soteria AI, Model AI-100
Intended Use	The Omega Medical Imaging, LLC CS-series-FP (SSXI) systems with optional accessory device CA-100S as a modification 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 Populations.	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 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:

It is detailed in the Bench testing section of this submission.

Safety information:

- The Omega Soteria.AI systems comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega Soteria.AI 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, EN ISO 15223-1, and EN ISO 14971.
- The Omega Soteria.AI 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 on October 2018)
- Guidance for the Content of Premarket Submissions for **Software Contained in Medical Devices** (Document issued on May 11, 2005)
- Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-powered Medical Devices.** (Document issued on July 11, 2016)
- 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 on October 2, 2017)
- Guidance for industry and FDA Staff - **Refuse to Accept Policy for 510(k)** (Document issued on September 2019)
- 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 on September 2019)
- Guidance for industry and FDA Staff - **Guidance for the Content of Premarket Submission for Software in Medical Devices.** (Document issued May 11, 2005)
- 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 on May 8, 2019)
- 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)