



Omega Medical Imaging, LLC  
c/o John Newman  
Manager of Regulatory Affairs  
3400 St. Johns Parkway, Suite 1020  
SANFORD, FL 32771

October 4, 2018

Re: K191713

Trade/Device Name: CS-series-FP Radiographic / Fluoroscopic Systems with Optional CA-100S / FluoroShield™ (ROI Assembly)

Regulation Number: 21 CFR 892.1650

Regulation Name: Image-Intensified Fluoroscopic X-Ray System

Regulatory Class: Class II

Product Code: JAA, OWB

Dated: May 2, 2019

Received: June 26, 2019

Dear John 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/pmnmn.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](mailto: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

## Indications for Use

510(k) Number (if known)

**K191713**

Device Name

CS-series-FP Radiographic / Fluoroscopic Systems with Optional CA-100S / FluoroShield (ROI Assembly)

Indications for Use (Describe)

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. At no time will the CA-100S be considered as a replacement for the primary collimator. The primary collimator shall always be used, in accordance with good medical practice, to define a Region of Interest

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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## **Traditional 510(k) SUMMARY**

K191713

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 (Manager of Regulatory Affairs)  
Date Prepared: 08/28/2019  
Device (trade) name: CS-series-FP Radiographic / Fluoroscopic Systems with Optional CA-100S / FluoroShield™ (ROI Assembly)  
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 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 Fluoroscopic / Radiographic Systems with Optional CA-100S (ROI Assembly) K182834  
Common/usual name: Fluoroscopic/Radiographic X-ray system  
Classification Name: Image-intensified fluoroscopic x-ray system  
Classification Panel: Radiology  
CFR section: 892.1650

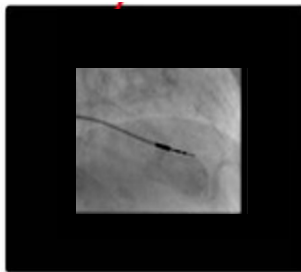
Device Class: Class II  
Primary Product code: JAA  
Secondary Product code: OWB

### Device description:

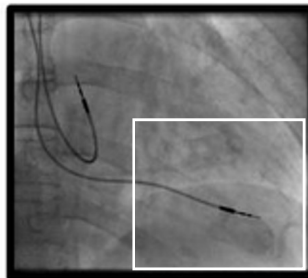
This 510(k) submission is for the addition of an optional secondary fast collimator system (Model: CA-100S / FluoroShield™ K182834 cleared 02/18/19). The CA-100S/ FluoroShield™ will be used with the following FDA cleared device: Omega's CS-series-FP ( K100102) which utilizes a Varex 2020 Flat Panel Detector. (Note: the only difference between this submission and the predicate is the size of the FPD. The predicate device utilizes a Varex 3030 Flat Panel Detector)

The-CA-100S/ FluoroShield™ system is composed of a **Shutter**, a **ROI Electronics Unit**, an **Auto-ROI Processor**, two **ROI Control Panels** and a **Monitor** (See Figure 1) .

Conventional Collimation



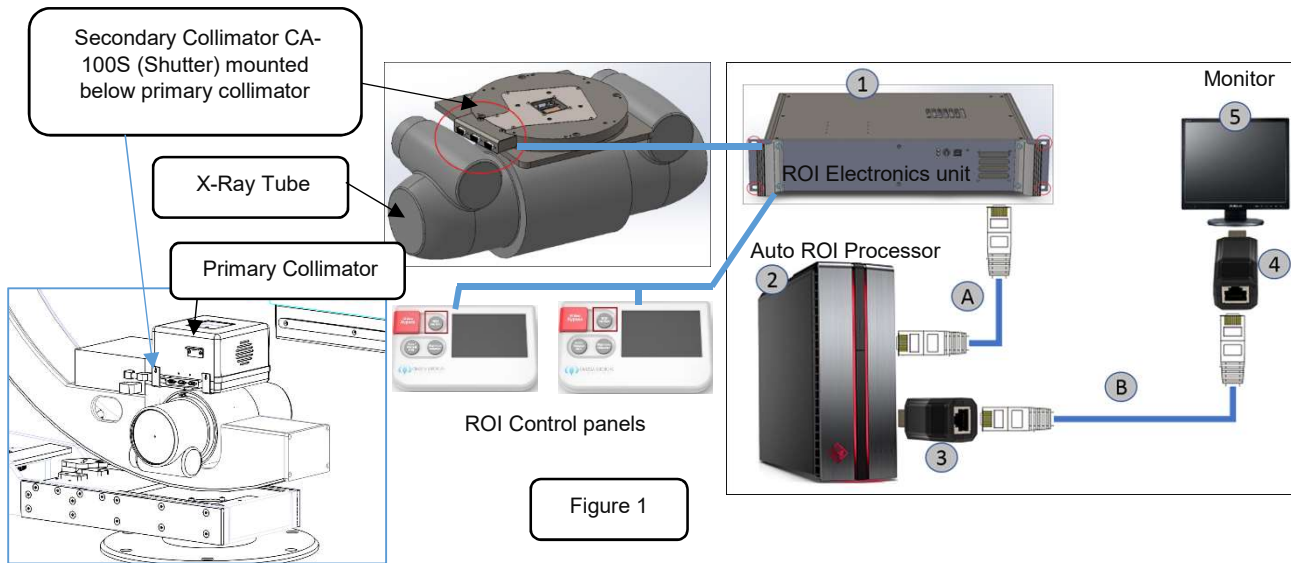
CA-100S/ FluoroShield™ Auto ROI



### Optimized Dose Reduction: Advanced Auto Collimation

Omega's (CA-100S/ FluoroShield™) allows for auto collimation while maintaining a perspective of surrounding anatomy. The blended image incorporates a lower frequency refresh of the peripheral image area. This combined image (live fluoroscopy of ROI + background refreshed at a rate of once or twice per second) increases the quality of information presented during interventional procedures.

- Image quality is improved via auto-collimation resulting in a reduced FOV and subsequently less X-ray scatter.
- Anatomical landmarks and devices visible outside the Region of Interest (ROI) provide important clinical information which are viewed at a reduced exposure level / Rate.
- The CA-100S can be sized and positioned in manual mode, as opposed to conventional collimation, which is generally limited to positioning about the center of the image.
- Auto ROI automatically follows the movement of devices i.e. endoscopes, catheters, etc., minimizing distraction and input requirements for the operator.



During a fluoroscopy procedure, the physician's attention is focused on a narrow region of interest (ROI) or a small region within the full field of view after collimating down to an area that will best suit the procedure with the primary collimator. (Figure 2)

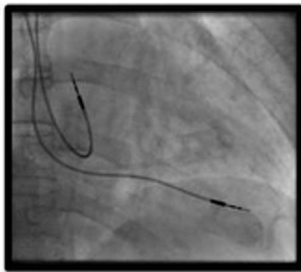


Figure 2, Primary / Conventional Collimator

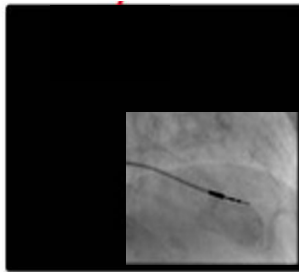


Figure 3, Secondary Collimator, CA-100S/FluoroShield™, Shutter



Figure 4, Blended image from both collimators.

This smaller region of interest (ROI) captured by the secondary collimator (CA-100S) is a small area within the area defined by the pre-existing primary collimator. (See Figure 3) The area outside the ROI receives much less attention by the physician but is exposed. The CA-100S secondary collimator may be used to additionally shield anatomy that is not the primary focus of the physician but is required to maintain peripheral imaging. The CA-100S ROI image processing combines the live ROI with the legacy image of the full field of view (defined by the primary collimator). This allows for the collimation of the ROI without impacting the doctors normal work flow, visualisation, orientation and navigation. (See Figure 4)

The ROI always contains the central beam for accurate calculations of Air Kerma values.

The CA-100S / FluoroShield™ offers additional collimation by shielding parts of the FOV outside the ROI without loss of visual information available to the physician or operator. the X-Ray Generator and Generator Interface are not changed. The system is configured with Omega's permanently floor mounted C-Arm that provides motorized positioning of the x-ray source and image receptor, along with a patient table with options for elevating and tilting.

- **System components integrated for this option are:**
  - CA-100S / FluoroShield™ secondary collimator Components detailed in Yellow.
  - Image Processor / Workstation
  - Associated electrical / electronic / hardware components (See illustration below)

Typical system configuration consisting of integrated components such as the X-Ray generator, Image Processor, collimator, X-ray Tube, Positioner and patient table.

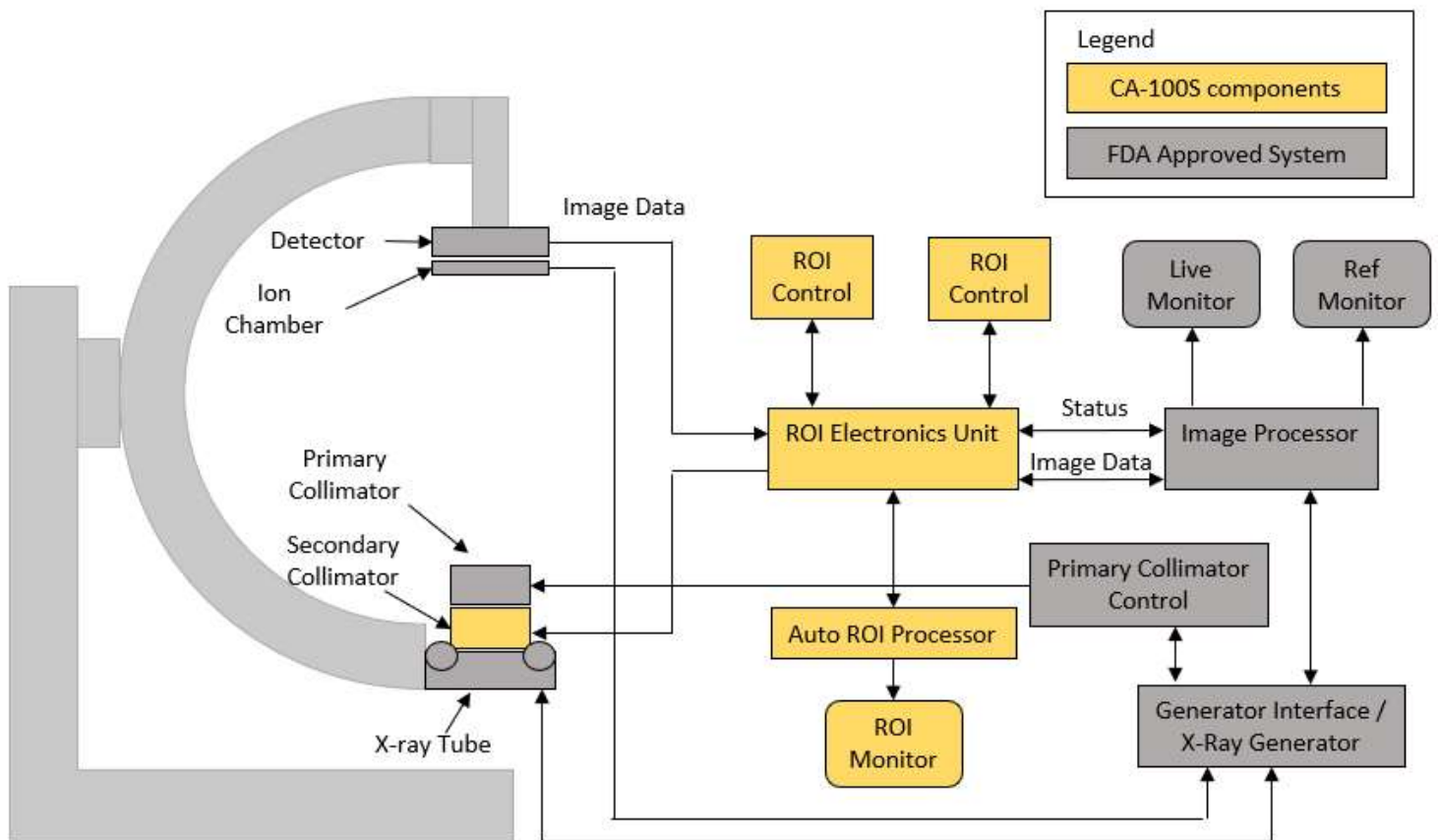
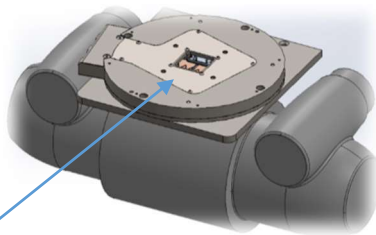


Figure 5

## OPERATION

The CA-100S / FluoroShield™ collimator is installed between the X-ray source and the primary collimator (See Figure 5). The opening of the secondary collimator shutters is adjustable in position. When the secondary collimator shutter function is enabled, only the ROI is continuously exposed and always includes the central beam from the X-ray tube **this does not affect Air Kerma rate, Accumulated Air Kerma or Accumulated Fluoro Time as calculations are derived from kV, mA, exposure time and SOD.** The secondary collimator shutter periodically opens fully to allow the acquisition of a FOV frame (defined by the primary collimator) that provides the background peripheral area. The image processing software then provides a combined, or “blended” image comprising the ROI frame and the most recently acquired FOV frame. The Product is permanently incorporated in the host fluoroscopy system (Omega’s CS-series-FP) and its clinical environment. The system is intended to be installed by trained technicians and operated by professionals trained in its use and the associated medical interventional procedures. The CA-100S/ FluoroShield™ Product functions in ON Mode, OFF Mode or Bypass Mode. In **ON Mode**, the secondary collimator shutter is activated, and the images are blended. In **OFF Mode**, the secondary collimator shutter is not driven, and the shutter blades are retracted fully while the images pass through both collimators without blending images (i.e. all image frames are FOV image frames defined by the primary collimator). In **BYPASS Mode**, the secondary collimator shutter driver is powered down (all shutter blades are retracted) and all received images bypass the CA 100-S/ FluoroShield™ image processing path. The Product consists of a **Shutter**, a **ROI Electronics Unit**, an **Auto-ROI Processor with Status / Reduction Monitor** and two **ROI Control Panels**. Their operations are described below.



### Shutter

The shutter consists of four lead blades that are moved into positions defined by the operator or automatically by the ROI Processor to determine and select the Region of Interest. Each shutter blade is moved by the application of a current which drives its magnetic coil. The electromotive force is counterbalanced by the retracting force of the spring. This current is limited to 1 Amp. The driving voltage is limited to  $\pm 30V$  peak.

The Shutter provides position feedback via low voltage (10V peak) signaling. Power for the feedback circuit is provided externally as 12V, limited to approximately 200mA. When not driven, the shutter is mechanically retracted by strong springs. In this state, it is essentially transparent to the optical path of the Host System.

Neither operators nor patients will come into contact with the shutter.

The enclosure is made of plated steel and aluminum. All moving parts and electrical components are completely enclosed. External electrical connections are made with shielded cables. Electrical components are galvanically isolated from the housing. The shutter and associated cables are enclosed by the housing of the Host System.





### **ROI Electronics Unit (“REU”)**

The REU controls the overall operations of the Product. It receives images from the receptor panel and transmits images to the Host System’s image processor. If the received image is an ROI frame, it combines the frame with the background from the most recent FOV frame.

The REU drives the four shutter blades through independent channels and receives position feedback through independent channels. The REU holds the blade positions constant while X-ray emission is in progress. The shutter blades are only moved when there is no X-ray emission.

The REU receives and responds to user inputs via the ROI Control Panels. (See section below for details.)

The REU receives and responds to signals representing the state of a fluoro sequence, the state of X-ray emission, the source-to-image distance, pending or in-progress table movement, flip and rotation offset, and magnification mode.

The REU sends positions of the boundaries of the ROI and the overall operating status to the Host System for display on its main screen.

The REU sends blended images to the Auto-ROI Processor and receives the calculated (recommended) locations for the shutter blades. In auto-ROI mode the REU drives the blades to these locations.

\*On detecting conditions that may compromise operations or longevity of the Product, the REU puts the Product in OFF Mode. On detecting conditions that may compromise the image, a loss of communication with, or control over, other modules, the REU puts the Product in Bypass Mode.

The REU is installed in an electronics cabinet. Neither operators nor patients will come into contact with the REU.

The REU’s electrical and electronic components are housed in a metallic enclosure. All panels of the enclosure are bonded to each other. A protective earth terminal is provided.

The REU is intended to operate on a 120/240 Vac, 50/60Hz, single-phase output from an uninterruptible power supply. The component power supply unit (“PSU”) is recognized to UL60950-1 and ES60601-1. The Earth terminal of the PSU is bonded to the enclosure.

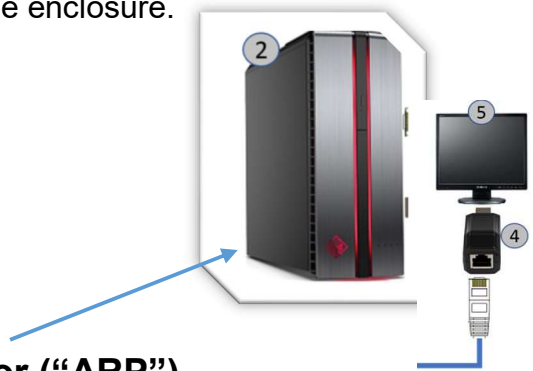


## ROI Control Panels (“RCP”)

A bedside RCP and a control room/booth RCP provide facilities for the user to control the operation of the Product. Four buttons and a trackpad are provided on each RCP to control ROI functionality.

The RCP communicates with the REU over a shielded cable which also carries 12V to power the RCP. The 12V power source provides 2A of current to both RCPs and other circuits drawing on this rail. Each RCP consumes about 100mA.

The RCP’s electrical and electronics components are fully enclosed in a metallic enclosure that provides ingress protection against fluids (jets or strong sprays). The trackpad is exposed to touch. The touch surface is tied to the enclosure and isolated from the rest of the circuits. A shielded cable connects the RCP to the REU. The shield of the cable is tied to the enclosure.



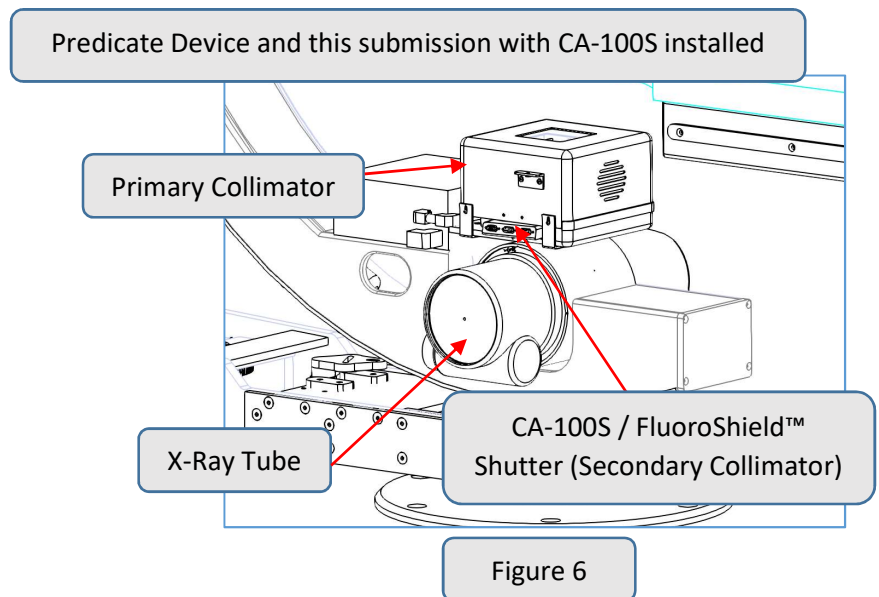
## Auto-ROI Processor (“ARP”)

A dedicated computing device receives and analyzes the processed images from the REU. From these images, the ARP calculates the ROI settings that provide the most useful image to the physician or operator. The ARP also generates display data that indicates the operating status and/or status messages. The ARP communicates with the REU via a single Gigabit Ethernet (“GigE”) connection over CAT5E or CAT6 copper cables with magnetic isolation at the connectors.

The ARP is enclosed in a metallic housing and is intended to be installed in a control room or electronics room. It is intended to operate on a 120Vac, 60Hz, single-phase output from an uninterruptible power supply.

**No Mechanical Differences other than the sized of the Flat Panel Detector between Predicate device and this submission:**

- No mechanical changes to mount the CA-100S Sutter under the Primary Collimator as illustrated in Figure 6. Both the predicate device and this submission utilize the same mechanical mounting for the CA-100S / FluoroShield™ Shutter assembly.



## **New and adapted Features for implementation of CA-100S into this submission:**

- This release provides both REU and ARP support for the Varex 2020 Panel based CA-100S system. There are no changes to the existing software that supports the Varex 3030 Panel Based CA-100S system.
- Image resolution: image width and height are set to 1024 to match the 2020 system resolution.
- Frame rate: image processing and display frame rates are set to 15 frames per second to match the 2020 system's effective frame rate.
- Frame duplication: system will replay the last good known frame when a dark frame (image with no matching X-RAY exposure) is input
- Blades' indices switch: The blade location index is updated to match the panel orientation of the 2020 system.
- Mag modes: Mag mode 1 and Mag mode 2 is set to 80% and 66.7% of normal mode (Mag mode 0) image size, respectively.

### **Auto ROI Processor Software**

- Image resolution: image width and height are set to 1024 to match the 2020 system resolution.
- Frame rate: image processing and display frame rates are set to 15 frames per second to match the 2020 system's effective frame rate.
- Ignore duplicate frames in image receiving: a received frame with the same ID as the previous frame is skipped for only processing valid frames (such ID duplication occurs due to the valid frame duplication in the REU to discard the 2020 system's alternation between valid and dark frames).
- Shutter's ROI size and path in calibration: the ROI's size used in calibration is reduced and its path is trimmed to match the narrower field of view of the 2020 system.
- Blades' indices switch in calibration: the blades' indices are re-assigned to match the panel orientation of the 2020 system.
- Segmentation model: updated model based on trained images from the 2020 system.
- Motion detection module and its incorporation in tracking: a module that computes motion detection between consecutive frames, based on which a motion map is generated to improve tracking of the ROI in combination with the segmentation map.
- Initial ROI size in Mag modes: the initial ROI in Mag mode 1 and Mag mode 2 is set to 80% and 66.7% of normal mode (Mag mode 0) image size, respectively.
- Prior probability in tracking and updated parameters: to improve ROI tracking performance.

**Reason for Submission:**

- Modification of a cleared device.

**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) CS-series-FP with optional CA-100S
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 <b>manages</b> 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. At no time will the CA-100S be considered as a replacement for the primary collimator. The primary collimator shall always be used, in accordance with good medical practice, to define a Region of Interest	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 <b>reduces</b> 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. At no time will the CA-100S be considered as a replacement for the primary collimator. The primary collimator shall always be used, in accordance with good medical practice, to define a Region of Interest
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**

The CA-100S / FluoroShield™ is a secondary collimator that can only be used in conjunction with the primary collimator. When using the CA-100S / FluoroShield™, the primary collimator shall be used to manually define a region of interest. Once this ROI has been established by the primary collimator, the CA-100S / FluoroShield™ can be used to further reduce the size of the ROI beyond the ROI initially established with the primary collimator. Due to the reduction in size of the ROI, the CA-100S/ FluoroShield™ can offer a reduction in Dose Area Product to patients and medical staff by reducing the area of exposure. At no time will the CA-100S/ FluoroShield™ be considered as a replacement for the primary collimator. The primary collimator shall always be used, in accordance with good medical practice, to define a ROI.

Additional testing for this submission was performed utilizing a DAP meter to demonstrate the dose reduction results utilizing the CA-100S / FluoroShield™ accessory. A clinical study was conducted sampling 100 patients as well to demonstrate the dose reduction to patients and staff.

- Predicate device Omega CS-series-FP utilizes the CA-100S.

- The only difference for this submission is use of the CA-100S with a smaller Varex 2020 FPD that is 20cm x 20cm versus the predicate device that utilizes a Varex 3030 FPD that is 30cm x 30cm.

### **Substantial Equivalence:**

- **SE** was determined on Bench performance testing. Included in this report is detailed data comparing performance with the existing Omega Medical Imaging CS-series-FP system utilizing the CA-100S integrated with the Varex 3030 FPD versus the Varex 2020 FPD. The tests that were performed utilized commercially available Phantoms such as the Phillips Phantom, and including a fabricated Moving Catheter to exercise the auto ROI functionality.
- Additional Testing utilizing a DAP meter to further demonstrate the reduction of Patient dose was conducted and demonstrated in house bench testing and a 3rd party Clinical Study. This substantiates our position in changing the IFU statement from "Manages exposure" to "Reduces exposure"

This device is substantially equivalent to *Omega Medical Imaging CS-series-FP Radiographic Fluoroscopy System with Optional Accessory Device CA-100S (ROI Assembly) K182834* marketed by Omega Medical Imaging LLC. *The Omega CS-series-FP with Optional accessory device Model CA-100S*. The basic system configuration, method of operation, base software and manufacturing process remain unchanged from the cleared device. The only difference is the size of the Flat Panel detector, Predicate device utilizes a Varex 3030 FPD, this submission utilizes a Varex 2020 FPD.

### **Safety information:**

- The Omega CS-series-FP with the CA-100S option systems comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega CS-series-FP with the CA-100S option 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 CS-series-FP with the CA-100S option 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 as 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 requirements of the Federal Diagnostic Equipment Standard, 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 is in compliance with the Quality System Regulations

### **Conclusion:**

- The technological characteristics of *Omega CS-series-FP with Optional accessory device Model CA-100S* is substantially equivalent to the *Omega Medical Imaging CS-series-FP*

*K182834*. This determination was made by comparing intended uses, designs, materials and performance. Any differences between the devices do not raise any issues of safety and effectiveness. It is the contention of Omega Medical Imaging that all new safety issues have been addressed in the design of this change and that adequate evidence of this is presented with this submission.

- It is believed that the clinical studies presented in this Submission, taken together with the extensive internal bench testing with FluoroShield™ are sufficient to support the safety and effectiveness of FluoroShield to reduce radiation during fluoroscopic imaging procedures. A prospective study of 100 consecutive patients who underwent fluoroscopy-guided endoscopic procedure. Patients underwent interventions utilizing either conventional fluoroscopy or FluoroShield™ fluoroscopy system to limit radiation exposure to the region of interest. There was no significant difference in demographics, body mass index, procedural type, procedural or fluoroscopy time between the conventional and the FluoroShield fluoroscopy systems.
- There were two main Objectives of this clinical study
  1. To compare and measure radiation exposure to patients by using dose area product (DAP).
  2. To compare and measure scatter radiation to endoscopy personnel measured using Landauer Luxel personal dosimetry badges.
- Clinical studies conducted showed When using FluoroShield, unnecessary radiation can be reduced up to **61.8%** in patients and **59.4%** to the staff. FluoroShield technology ensures radiation safety while maintaining image quality so physician and staff can continue to perform interventional procedures on patients effectively.
- The use of the CA-100S / FluoroShield™ is consistent with a best medical practice for interventional fluoroscopy with FluoroShield, which in real-time optimizes image quality in the region of interest while reducing unnecessary radiation in the periphery.
- Taken together, the clinical trials and in-house testing reports presented in this Submission are believed to be sufficient to support the safety and effectiveness of FluoroShield in reducing unnecessary radiation exposure to both patient and staff. This also substantiates the decision to modify the Indications for Use statement by changing the phrase: "Manages exposure" to "Reduces Exposure"
- The FluoroShield™ was fully integrated with the Varex 2020 FPD, Image Processor ARP processor, ROI electronics and all supporting equipment to establish full functionality and integration into Omega Medical Imaging host system including Verification and Validation of Software and operational functions.
- Product verification plan and the Test Reports are written in accordance to applicable regulations Historically, OMI includes the purpose (test objectives) scope and lists methods (test instructions) within one design verification protocol and captures the results in one report. The full validation/Verification and test report for this project were included.

The functional test also serves as the validation of the software modules whose outputs are observable in system behavior and effects on, or interaction with, the fluoroShield™

- OMI does not create separate test reports and protocols for each test. A table listing all the testing performed to ensure full integration of the system is indicated below in Table 1.
- OMI has established Test Instructions that were utilized to perform and record all of the Design Verification tests identified in Protocol after a full integration of the device into a host system. These controlled test instructions were explicitly created for the CA-100S / FluoroShield™ with a Varex 2020 PFD but have been based on OMI's experience with previous CA-100S with a Varex 3030 FPD device project. Within each Testing Instruction, the Purpose, Contents (testing material and equipment) and Data Recording are defined. These Test Instructions were referenced in the Design Verification the Testing Instructions are listed in Table 1 below:

Test Description:	Reference:	Section:
Calibration Process	Doc#IK08-0118	7.1
Power- On	Doc#IK08-0118	7.2
ROI Control Panel	Doc#IK08-0118	7.3
Host System Communication via Relays	Doc#IK08-0118	7.4
Mag Modes	Doc#IK08-0118	7.5
Responses to MX- Ikomed Serial Link	Doc#IK08-0118	7.6
Responses to Abnormal Condition	Doc#IK08-0118	7.7
Responses to Abnormal Signals	Doc#IK08-0118	7.8
Video Bypass Button	Doc#IK08-0118	7.9
Housekeeping Task	Doc#IK08-0118	7.10
Auto ROI Processor Access	Doc#IK08-0118	7.11
Video Quality	Doc#IK08-0118	7.12
Shutter Blade Position Consistency	Doc#IK08-0118	7.13
Shutter Vibration	Doc#IK08-0118	7.14

**Table 1**



## 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<sup>th</sup>, 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 2, 2014)
- 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 January 30, 2018)
- Guidance for industry and FDA Staff -**Format for Traditional and Abbreviated 510(k)s** (Document issued on August 12, 2005)
- 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 9, 1999)
- Guidance for industry and FDA Staff - **Guidance for the Content of Premarket Submission for Software in Medical Devices**. (Document issued February 3, 2016)
- 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)