April 30, 2025

A.T.S. Applicazione Tecnologie Speciali s.r.l.
℅ Francesca Pedretti
Quality Management System and Regulatory Affairs Manager
Via Alessandro Volta, 10
TORRE DE' ROVERI, BG 24060
ITALY

Re: K250282
Trade/Device Name: Persona C HR
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO
Dated: January 30, 2025
Received: January 31, 2025

Dear Francesca Pedretti:

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 Radiological Imaging
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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.

510(k) Number *(if known)*
K250282

Device Name
Persona C HR

Indications for Use *(Describe)*
PERSONA C HR is a mobile X-ray device used for radiological guidance and visualization during diagnostic, interventional and surgical procedures.
PERSONA C HR device can be used on all patients, except pediatric patients, within the limits of the device.
Examples of clinical applications could be Orthopedic surgery, General surgery, Cardiac procedures, Thoracic surgery, Vascular procedures, Pain therapy and Urological procedures.

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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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue Silver Spring,
MD 20993-0002

April 30th, 2025

In accordance with 21CFR §807.92 the following 510(k) summary information is provided:

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Proposed Device

Device Common Name:	Interventional Fluoroscopic C-arm
Trade Name:	PERSONA C HR
Submission number	K250282
Classification Name:	Image-intensified fluoroscopic x-ray system (21 CFR, Part 892.1650)
Product Code:	OWB, OXO
Regulatory Class:	II

Predicate Device

Device Common Name:	Interventional Fluoroscopic C-arm
Trade Name:	ARCO FP
Submission number	K182086
Classification Name:	Image-intensified fluoroscopic x-ray system (21 CFR, Part 892.1650)
Product Code:	OWB, OXO
Regulatory Class:	II

Device Description:

PERSONA C HR is a C-arm mobile unit with flat panel detector.

It allows imaging under the following modes:

- Low Dose Fluoroscopy,
- High Quality Fluoroscopy,
- High Quality + Fluoroscopy
- Digital radiography (Snapshot),
- Fluoroscopy in Road Mapping mode (optional),
- Fluoroscopy in DSA mode (optional).

It is provided with a 30x30 cm Flat Panel detector and a 25 kW X-ray generator.

The unit is composed of: Monitor unit, Stand with c-arm, X-ray commands, Printer (optional).

The device acquires images employing X-rays emitted by an X-ray source which can produce up to 25kW.

The unit, which is powered by a single-phase electrical supply, generates ionizing radiations (X-rays) which, as they pass through the patient, reach a flat panel detector that produces radiological images.

An x-ray collimator, placed on the monobloc, is responsible for limiting the emission beam of ionizing radiation.

The images collected by the detector are sent to a video processor, which, after processing the information received, allows radiological images to be displayed on the display monitor.

The proposed device PERSONA C HR is substantial equivalent to the currently marketed predicate device ARCO FP (K182086), in terms of indications for use, fundamental scientific technology, safety and effectiveness. Software and firmware architecture designs are identical to those of the predicate ARCO FP (K182086).

Indications for Use:

PERSONA C HR is a mobile X-ray device used for radiological guidance and visualization during diagnostic, interventional and surgical procedures.

PERSONA C HR device can be used on all patients, except pediatric patients, within the limits of the device.

Examples of clinical applications could be Orthopedic surgery, General surgery, Cardiac procedures, Thoracic surgery, Vascular procedures, Pain therapy and Urological procedures.

The intended use is substantially equivalent to that of the predicate device ARCO FP (K182086).

Summary of technological characteristics:

PERSONA C HR device employs X-rays as its imaging technology for visualizing human anatomy. The X-ray tube in the monobloc produces X-rays, which as they pass through the patient, reach a flat panel detector for visualizing radiological images. An x-ray collimator, placed on the monobloc, is responsible for limiting the emission beam of ionizing radiation (X-rays). The images collected by the detector are sent to a video processor which, after processing the information received, allows radiological images to be displayed on the display monitor.

The images from the device assist the physician in visualizing the patient's anatomy. This visualization helps to localize regions of pathology and for surgical procedures.

The PERSONA C HR C-arm mobile unit is a flat panel detector and fluoroscopic X-ray imaging system consisting of a Stand (C-arm) and a Monitor unit. The main components of the Stand are

a monobloc with high voltage generator (with rotating anode tube and cooling system), an X-ray collimator, and a flat panel detector (FDP). The C-arm supports the monobloc and the flat panel detector (FPD) on opposite sides. The Monitor unit is a mobile platform connected to the Stand by a cable.

The proposed modified device PERSONA C HR employs the same fundamental control, and substantially equivalent scientific technology as that of the predicate device ARCO FP (K182086).

Software architecture design is substantially equivalent to that of the predicate device ARCO FP (K182086).

The primary modifications to the predicate device ARCO FP (K182086) are:

- an aSi-IGZO (Indium gallium zinc oxide) flat panel detector (FPD) which has substantially equivalent technology characteristics as the predicate device ARCO FP (K182086).
  The system design and housing are identical to the Predicate ARCO FP K182086 and both detectors use safety shielding for radiation suppression and use solid state x-ray image receptors (SSXI/FDP).
  The new generation aSi-IGZO detector of the proposed device allows faster speed and better performances (up to 30 fps always at full resolution) respect to the one of the predicate device ARCO FP (K182086).

- A max power output 25kW generator instead of 20kW. The generator has the same technological characteristics as the predicate device ARCO FP (K182086).

- The monitor unit is composed by a single 32" Monitor instead of the two 21,5" Monitors of ARCO FP (K182086) predicate device. The technological characteristics of the monitor of the proposed device PERSONA C HR and the predicate device ARCO FP (K182086) are equivalent.

- A new Control panel, the successor to the one mounted on the predicate, with a 13" screen instead of 12".

The comparison of the predicate device and the proposed device shows that the scientific and technical characteristics of PERSONA C HR are substantially equivalent to those of ARCO FP (K182086) predicate device.

Substantial equivalence discussion

The changes of the proposed device PERSONA C HR, described in the table, do not change the fundamental control mechanism, operating principle, energy type, and intended use found on predicate device (ARCO FP K182086) and are substantially equivalent to the predicate device.

Differences between the predicate device (ARCO FP) and the proposed device (PERSONA C HR) **do not raise new safety or effectiveness concerns.**

Comparison Chart	PROPOSED DEVICE PERSONA C HR	PREDICATE DEVICE ARCO FP	Substantial equivalence discussion
510(k) Number	*K250282*	*K182086*	-
CLASS	2	2	*Identical*
Product code	OWB	OWB	*Identical*
Secondary Product code	OXO	OXO	*Identical*
Intended Use			
	PERSONA C HR is a mobile X-ray device used for radiological guidance and visualization during diagnostic, interventional and surgical procedures. PERSONA C HR device can be used on all patients, except pediatric patients, within the limits of the device. Examples of clinical applications could be Orthopedic surgery, General surgery, Cardiac procedures, Thoracic surgery, Vascular procedures, Pain therapy and Urological procedures.	ARCO FP is a mobile X-ray device used for radiological guidance and visualization during diagnostic, interventional and surgical procedures. In particular, the device is to be applied during orthopaedic, neuro, abdominal, vascular, thoracic, and cardiac procedures. ARCO FP device can be used on all patients, except paediatric patients, within the limits of the device.	*Substantially equivalent*
PERFORMANCE SPECIFICATION			
	PROPOSED DEVICE PERSONA C HR	**PREDICATE DEVICE ARCO FP**	
Mechanical size and weight			
Stand	195 (L) x 89 (W) x 161 (H) 280 kg	195 (L) x 89 (W) x 161 (H) 280 kg	*Identical*

Comparison Chart	PROPOSED DEVICE PERSONA C HR	PREDICATE DEVICE ARCO FP	Substantial equivalence discussion
510(k) Number	*K250282*	*K182086*	-
Monitor Trolley	76,4(L) x 76,4(W) x **152**(H) 140 kg	76,4(L) x 76,4(W) x 158(H) 140 kg	*Substantially equivalent*
Electrical requirements			
Supply type	Single phase (live/neutral, separate earth)	Single phase (live/neutral, separate earth)	*Identical*
Input Voltage	**120 V, 230 V @50-60Hz**	100, 110, 120, 130 V 210, 220, 230, 240 V @50-60Hz	*Substantially equivalent.* *The available supply voltage has been limited because the removed ones are not required by the distributor. The insulation transformer and other power circuitry are identical.*
X-ray generator *(see Device Description, Paragraph 3.7)*			
Max parameters	**25kW:** - 120 kV - **200 mA (fluoroscopy)** - **250mA (digital RAD)**	5kW: - 120 kV - 40 mA (fluoroscopy) - 32,5 mA (digital RAD) 20kW: - 120 kV - 100 mA (fluoroscopy) - 200 mA (digital RAD)	*Substantially equivalent.* *The proposed device has a higher max power output (25kW: 100kV-250mA), using the same housing, x-ray tube, and monobloc thus keeping the same dimensions.*

Comparison Chart	PROPOSED DEVICE PERSONA C HR	PREDICATE DEVICE ARCO FP	Substantial equivalence discussion
510(k) Number	*K250282*	*K182086*	-
Fluoroscopy: Pulse and duration	Pulse Rate: 1,2,4,8,15,**30** Pulse width (msec): 7 - **8*** - **10*** - 16 - 20 - 40	Pulse Rate: 1,2,4,8,15 or 1,3,6,12,25 Pulse width (msec): 7- 13 - 16 - 20 - 40	*Substantially equivalent.* *General system exposure control technology and operational functionality are identical to the Predicate ARCO FP K182086* **Pulse width shortened to allow 30 fps, also result in maintaining very similar patient dose level.*
Monobloc Thermal Management	Active cooling *It allows to increase the heat dissipation, thus increasing the operating time.*	Passive cooling	*Substantially equivalent.* *The x-ray part (tube, housing, control circuitry, etc) are basically the same as the Predicate device ARCOFP.*
***Booster capacitors group** (see Device Description, Paragraph 3.14)*			
Booster	64.800 µF capacitors	30.000 µF capacitors	*Substantially equivalent.* *The system design and housing are identical to the Predicate ARCO FP K182086.*
***X-ray tube** (see Device Description, Paragraph 3.3 Technical Data)*			

Comparison Chart	PROPOSED DEVICE PERSONA C HR	PREDICATE DEVICE ARCO FP	Substantial equivalence discussion
510(k) Number	*K250282*	*K182086*	-
Rotating anode	Same model	Same model	*Identical*
Collimator *(see Device Description, Paragraph 3.11 X-Ray Collimator)*			
Collimator	Possibility of asymmetrically move the parallel shutters.	Symmetrical movement of the parallel shutters.	*Substantially equivalent.*
Anti-scatter grid *(see Device Description, Paragraph 3.3 Technical Data)*			
Removable grid	Same model	Same model	*Identical*
Laser centering device *(see Device Description, Paragraph 3.3 Technical Data)*			
Pointer	CLASS 1M (Red light) 635 nm **CLASS 1 (Green light) 515 nm**	CLASS 1M (Red light) 635 nm	*Substantially equivalent.* *The system design and housing are identical to the Predicate ARCO FP K182086.*
Image detector *(see Device Description, Paragraph 3.6 Flat Panel Detector)*			
Technology	- Amorphous Silicon Flat Panel Detector aSi-IGZO. - Scintillator: Cesium-Iodide (CsI)	- Amorphous Silicon Flat Panel Detector (aSi). - Scintillator: Cesium-Iodide (CsI)	*Substantially equivalent.* *This new generation aSi- IGZO detector allows faster speed and better performance (up to **30 fps** always at **full resolution**).* *The system design and housing are identical to the Predicate ARCO FP K182086.*
Dimension	30 x 30 cm	30 x 30 cm or 21 x 21 cm	*Substantially equivalent.*

Comparison Chart	PROPOSED DEVICE PERSONA C HR	PREDICATE DEVICE ARCO FP	Substantial equivalence discussion
510(k) Number	*K250282*	*K182086*	-
Features	- **Detector matrix: 2048 x 2048 pixels** - **Zoom field 1: 1440 x 1440 pixels** - **Zoom field 2: 1104 x 1104 pixels** - **Scintillator CsI** - **DQE (@9µGy, RQA5):** **72% @ 0 lp/mm** **56% @ 1 lp/mm** **44% @ 2 lp/mm**	- Detector matrix: 1956 x 1956 pixels - Zoom field 1: 1344 x 1344 pixels - Zoom field 2: 1024 x 1024 pixels - Scintillator CsI - DQE (@2µGy, RQA5): 77% @ 0 lp/mm 57% @ 1 lp/mm 48% @ 2 lp/mm	*Substantially equivalent.*
	Considering that the two values were measured at different doses, they are comparable and found to be substantially equivalent.		
	- **MTF:** **56% @ 1 lp/mm** **27% @ 2 lp/mm** - **Pixel size 146 µm**	- MTF: 59% @ 1 lp/mm 29% @ 2 lp/mm - Pixel size 154 µm	
Monitors *(see Device Description, Paragraphs 3.12 Monitor and 3.8 Control Panel, respectively)*			
Display	- **1x 32" LCD UHD** - **3840 x 2160 pixels (4K)** - **850 cd/m² (typ.)**	- 2x 21,5" LCD full HD - 1920 x 1080 pixels - 600 cd/m² (typ.)	*Substantially equivalent* *Higher brightness and resolution.*
Control Panel	- **13,3"** - **1920 x 1080 pixels** - **400 cd/m² (typ.)**	- 12,5" - 1920 x 1080 pixels - 400 cd/m² (typ.)	*Substantially equivalent*
X-ray switches *(see Device Description, Paragraph 3.15 X-Ray Commands)*			

Comparison Chart	PROPOSED DEVICE PERSONA C HR	PREDICATE DEVICE ARCO FP	Substantial equivalence discussion
510(k) Number	*K250282*	*K182086*	-
X-ray footswitch 	Same model	Same model	*Identical*
X-ray handswitch 	Same model	Same model	*Identical*
X-ray handswitch (pushbutton) 	**Two-pushbuttons handswitch**	Not provided	*Substantially equivalent.* *Additional pushbutton duplicating the footswitch function*
Image acquisition modalities *(see Device Description, Paragraph 3.5 X-Ray emission modes)*			
Fluoroscopy	- Fluoro LD - Fluoro HQ - **Fluoro HQ +** - RoadMap - DSA	- Fluoro LD - Fluoro HQ - RoadMap - DSA	*Substantially equivalent.* *New generator and booster group allow to reach higher mA curve (6), associated with the new acquisition modality.*
Video Processor *(see Device Description, Paragraph 3.3 Technical Data)*			

Comparison Chart	PROPOSED DEVICE PERSONA C HR	PREDICATE DEVICE ARCO FP	Substantial equivalence discussion
510(k) Number	*K250282*	*K182086*	-
PC host	- **CPU:** **Intel i7, 11700, 2,5GHz, Rocket Lake.** - **Operating system:** **WINDOWS 10 IoT Enterprise 2019 LTSC (ESD) ENG 64bit.** - **RAM: 16 Gb or more** - **Hard disk:** **HD SATA 3, 1Tb or more**	- CPU: Intel i5, 6400, 2,7GHz, Sky Lake. - Operating system: WINDOWS 7 embedded ENG 64bit. - RAM: 16 Gb. - Hard disk: HD SATA 3, 500 Gb.	*Substantially equivalent.* *Technological evolution.*

Summary of non-clinical and clinical test data:

PERSONA C HR is based on direct modifications to cleared predicate device ARCO FP (K182086).

The design of the modified PERSONA C HR was completed in accordance with A.T.S. Applicazione Tecnologie Speciali Quality Management System Design Controls, 21 CFR 820 and applicable standards. Verification and Validation testing were successfully conducted on the device in compliance with FDA requirements as stated in the provided documentation.

Non-clinical performance testing has been performed on the proposed PERSONA C HR and it demonstrates compliance with the following International and FDA-recognized consensus standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)].

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
  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 2.2 2021-01 CONSOLIDATED VERSION
  Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.

- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
  Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

- IEC 60601-2-43 Edition 3.0 2022-12
  Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures.

- IEC 60601-2-54 Edition 2.0 2022-09
  Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.

Both the equipment documentation and the tests carried out are in compliance with:

- "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*" guidance,

- "*Content of Premarket Submissions for Device Software Functions*" guidance.

Further, the device meets all applicable sections of 21 CFR Subchapter J.

The flat panel detector documentation provided in this submission demonstrates compliance of the modified device PERSONA C HR to "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices".

The modified device PERSONA C HR development occurred under our design control processes, software development processes, and overall quality management system.

The device has been demonstrated to be substantially equivalent to the identified predicate device. It has the same intended use and incorporates technological characteristics that are either identical or substantially equivalent. Substantial equivalence was supported by engineering-based performance testing, including evaluation of image quality using test phantoms and cadaver images by an "American Board of Radiology" radiologist.

System safety and effectiveness have been appropriately validated in accordance with FDA-recognized standards and guidances.

Conclusions drawn from nonclinical and clinical tests:

The verification/validation activities successfully confirmed device requirements have been fulfilled, system functionality is consistent with the user needs, intended use, and performs as designed, and raises no new questions regarding either safety or effectiveness.

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device ARCO FP (K182086).

Sincerely,

Stefano Daniotti
CEO