A.T.S. Applicazione Tecnologie Speciali S.R.L
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

August 13, 2021.

Re: K211777
Trade/Device Name: ARCO FP-S
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO
Dated: June 2, 2021
Received: June 9, 2021

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211777

Device Name
ARCO FP-S

Indications for Use *(Describe)*
ARCO FP-S is a mobile X-ray device with a Flat Panel detector used for radiological guidance and visualization during diagnostic, interventional and surgical procedures.
In particular, the device is to be applied during othopaedic, neuro, abdominal, vascular, thoracic and cardiac procedures.
ARCO FP-S device can be used on all patients except paediatric patients within the limit of the device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K211777

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Date Prepared: July 19, 2021

1. **Administrative Information**

Submitter:

Submission contact person: Eng. Livia PILLITTERI, QMS & Regulatory Affairs Manager

Identification:

Identification:	ARCO FP-S
Regulation Number:	21 CFR 892.1650
Regulation Name:	Image-intensified fluoroscopic x-ray system
Regulatory Class:	Class II
Product Code:	OWB, OXO

This is a MODIFIED device. The digital x-ray receptor panels have changed.

Substantially equivalent device: K182086

Manufacturer:	A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI S.R.L.
Trade/Device Name:	ARCO FP
Regulation Number:	21 CFR 892.1650
Regulation Name:	Image-intensified fluoroscopic x-ray system
Regulatory Class:	Class II
Product Code:	OWB, OXO

REFERENCE Device: (New digital x-ray receptor panels)
K200022 submitted by Livermoretech
Trade/Device Name: FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA, IZI

2. **Indications for Use:** ARCO FP-S is a mobile X-ray device with a Flat Panel detector used for radiological guidance and visualization during diagnostic, interventional and surgical procedures. In particular, the device is to be applied during orthopedic, neuro, abdominal, vascular, thoracic and cardiac procedures. ARCO FP-S device can be used on all patients except pediatric patients within the limit of the device.

3. **Device description:** ARCO FP-S is a mobile C-arm with the solid-state image detector "Flat Panel"
It will be realized in 2 models, depending on the size of the detector:
Model: ARCO FP-SR21

Dual focus 0.3/0.6 mm, rotating anode X-Ray tube, generator nominal power 5 KW.
Detector size 21x21 cm, 1024x1024 pixel.

Models: ARCO FP-SR30

Dual focus 0.3/0.6 mm, rotating anode X-Ray tube, generator nominal power 5 KW.
Detector size 30x30 cm, 1536 x 1536 pixel.

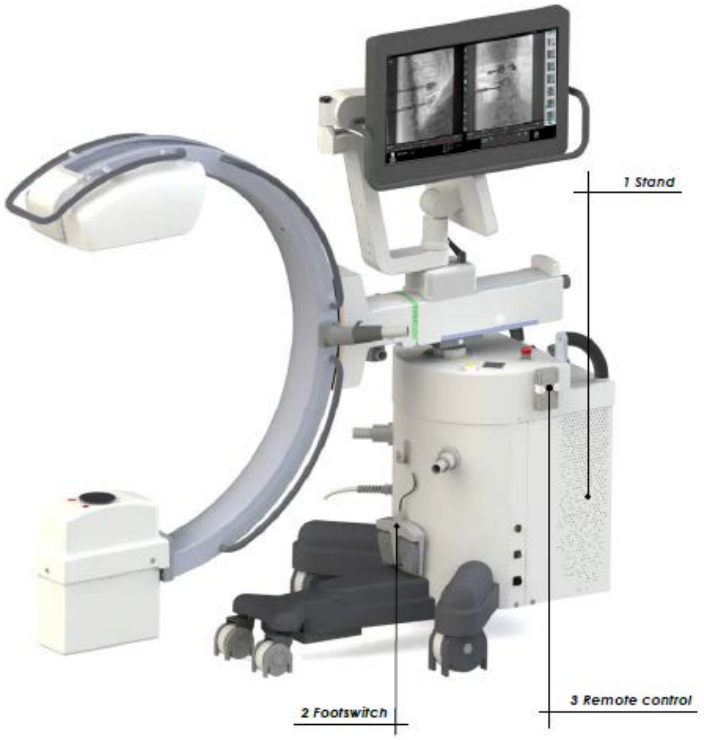

Photo: ARCO FP-S

OPTIONAL STAND: Wireless Monitor

The system consists of:

C-arm Stand:

- MECHANICAL STAND
- X-RAY MONOBLOC, rotating anode
- FLAT PANEL DETECTORS: 2121cm or 3030cm
- MONITOR LCD 27” QUAD HD format 16:9
- CONTROL PANEL
- X-RAY COLLIMATOR
- SYSTEM CONTROLLER
- X-RAY HAND SWITCH
- ARTICULATED ARM FOR MONITOR SUPPORT
- ANTISCATTERING GRID

Options:

- FOOTSWITCH, two-foot pedal
- LASER LOCALISER
- Dose Area Meter,
- DSA Packages

- I.R. remote controls.
- DICOM Classes
- EXTERNAL VIDEO OUTPUT-Wireless transmission
- DICOM DATA Wi-Fi transmission to Ethernet/PACS
- NFC LOGIN
- Wireless monitor trolley, model TROTTER W, for duplicating the image of the monitor on board.

Technology Employed

ARCO FP-S is a mobile C-arm unit for fluoroscopy and radiography designed for a wide rangeof surgical applications.
The normal use allows for imaging in the following modes:

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

The image acquisitions employ X-rays emitted by an X-ray generator which can produce upto 5 kW.
The X-rays, attenuated in different ways depending on the tissue they have to pass through, leave an impression on a detector and then they are converted into electrical signal, which forms the image.
The main differences from the predicate device are:
The image detectors are new. The Pixium detectors (used in the predicate device) were replaced with Paxscan (used with the subject device, cleared under K200022).
Only the 5 kW power generator is now available.
The software has been upgraded from the predicate software but the software functionality remains the same. The original software (SYSTEMA dRF- software ISIX) and the modified software (SYSTEMA DRF-S software) are FUNCTIONALLY IDENTICAL.
The workstation image display monitor is being upgraded to a higher resolution.
The operating system is upgraded (Windows 7 is no longer supported).

4. **Technological characteristics**: Comparison Table

Comparison Chart	**PROPOSED DEVICE ARCO FP-S**	**PREDICATE DEVICE ARCO FP K182086**
INDICATIONS FOR USE	ARCO FP-S 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 orthopedic, neuro, abdominal, vascular,thoracic and cardiac procedures. ARCO FP-S device can be used on all patients except pediatric patients, within the limits ofthe device.	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 orthopedic, neuro, abdominal, vascular,thoracic and cardiac procedures. ARCO FP device can be used on all patients except pediatric patients, within the limits ofthe device.
CLASS	2	2

Comparison Chart	PROPOSED DEVICE ARCO FP-S	PREDICATE DEVICE ARCO FP K182086
Product code	OWB; OXO	OWB: OXO
Photo		
PERFORMANCE SPECIFICATION		
A. C-arm		
C-Arm Weight	310 kg	280 kg
B. Power Supply		
Supply type	Single phase (live/neutral,separate earth)	Single phase (live/neutral,separate earth)
Input Voltage	100, 110, 120, 130, 210, 220, 230, 240 V @50-60Hz	100, 110, 120, 130, 210, 220, 230, 240 V @50-60Hz
X-ray Generator Maximum power	5kW	5kW; 20kW
C. X-ray tube		
Type	Rotating anode	Rotating anode
Nominal voltage	120 kV	120 kV
Nominal focal spot valuesinput power	0.3 mm = 6.0kW 0.6 mm = 25 kW	0.3 mm = 6.0kW 0.6 mm = 25 kW
Maximum heat dissipation	750 W	750 W
Maximum anode heat	225 kJ	225 kJ

Comparison Chart	PROPOSED DEVICE ARCO FP-S		PREDICATE DEVICE ARCO FP K182086	
content				
Anode material	Rhenium-Tungsten-Molybdenum		Rhenium-Tungsten-Molybdenum	
Filtration	Possible Filters To Apply: - none - 2mmAl - 1mmAl + 0,1mmCu - 1mmAl + 0,2mmCu		Possible Filters To Apply: - none - 2mmAl - 1mmAl + 0,1mmCu - 1mmAl + 0,2mmCu	
D. Detector				
	PaxScan 2121DXV	**PaxScan 3030DXV**	**PIXIUM 2121S**	**PIXIUM 3030S**
Active detector size / Sensitive area	1024x1024 pixel 205x205 mm	1516x1516 pixel 294x294 mm	1344 x 1344 pixel 207x207 mm	1956 x 1956 pixel 301x301 mm
Pixel size	205 µm	194 µm	154 µm	154 µm
Cooling	Passive		Passive	
Detective Quantum Efficiency, RQA5 [Lp/mm@2uGy]	0 –80%	0 –80%	0 –77%	0 –77%
	1.0 – 65%	1.0 – 65%	1.0 – 56%	1.0 – 57%
	2.0 – 40%	2.0 – 44%	2.0 – 46%	2.0 – 48%
Modulation Transfer Efficiency (MTF) [Lp/mm@2uGy]	1.0 – 50%	1.0 – 55%	1.0 – 59%	1.0 – 59%
	2.0 – 22%	2.0 – 23%	2.0 – 29%	2.0 – 29%
	Nyquist – 15%	Nyquist – 15%	Nyquist–11%	Nyquist–11%
Maximum frame per second	30		25	
E. Anti-Scattering Grid				
Material	Aluminum		Aluminum	
Lines/cm	80		80	
Grid focus distance	100 cm		100 cm	

Comparison Chart	PROPOSED DEVICE ARCO FP-S	PREDICATE DEVICE ARCO FP K182086
Ratio	8:1	8:1
F. Workstation monitor		
Size / Type	21.7'' / LCD	21.5'' / LCD
Resolution	2560 x 1440 (4K)	1920 x 1080
Nominal light output	350 cd/m^2	1000 cd/m^2
G. Control panel monitor		
Size / Type	12.5'' / LCD touch	12.5'' / LCD touch
Resolution	1920 x 1080	1920 x 1080
H. Workstation Operating system		
Windows version	Windows 10 (Windows 7 is no longer supported)	Windows 7 or Windows 10

5. Non clinical testing: In order to demonstrate the EMC and Electrical safety of the proposed device ARCO FP-S, the manufacturer A.T.S. Applicazione Tecnologie Speciali Srl. has performed safety tests incompliance with the standards listed here below:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basicsafety and essential performance;
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements forbasic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests;
- IEC 60601-1-3: Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation ProtectionIn Diagnostic X-Ray Equipment;
- IEC 60601-1-6: Medical Electrical Equipment - Part 1-6: General Requirements ForBasic Safety And Essential Performance - Collateral Standard: Usability;
- IEC 60601-2-43: Medical Electrical Equipment - Part 2-43: Particular RequirementsFor The Safety And Essential Performance Of X-Ray Equipment For Interventional Procedures;
- IEC 60601-2-54: Medical Electrical Equipment - Part 2-54: Particular RequirementsFor The Basic Safety And Essential Performance Of X-Ray Equipment For Radiography And Radioscopy.
- IEC 60825-1: Safety of laser products - Part 1: Equipment classification andrequirements
- IEC 62304: Medical device software - Software life cycle processes
- ETSI EN 301 489-17: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for Electro Magnetic Compatibility

In order to demonstrate the performance of the ARCO FP-S, the following quality testing has been performed by A.T.S. Applicazione Tecnologie Speciali Srl:

- Radiologist's Images evaluation. A Board Certified Radiologist reviewed the still and moving images

acquired by the newer digital receptor panels and found them to be of good and acceptable diagnostic quality.

The software remains at a *MODERATE LEVEL OF CONCERN*, and software was validated according to the FDA Software Guidance at that level.
The following FDA guidance was employed in regard to cybersecurity concerns: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff.* Our labeling and internal procedures were updated to reflect the recommendations of this guidance.

6. Clinical testing. Clinical Images are not necessary to establish substantial equivalence to the predicate. Adequate bench testing results should clearly indicate device safety and effectiveness.

7. Substantial Equivalence Discussion.

The ARCO FP-S performs the same functions as the predicate using the same technological methods to produce and store diagnostic x-ray images. In all material aspects, the A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI S.R.L. devices are substantially equivalent to each other. The detector technological characteristics (resolution, MTF and DQE performance, see comparison table above) all point to substantial equivalence

8. Substantial Equivalence Conclusion:

After analyzing bench test results, risk analysis, and standards compliance, it is the conclusion of A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI S.R.L.. that the ARCO FP-S is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.