March 15, 2024

Siemens Medical Solutions USA, Inc
% Patricia Jones
Regulatory Affairs Professional
40 Liberty Blvd
MALVERN, PA 19355

Re: K233748
Trade/Device Name: CIARTIC Move (VB10)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: February 14, 2024
Received: February 14, 2024

Dear Patricia Jones:

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.

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,

Gabriela M. Rodal -S

Digitally signed by Gabriela M. Rodal -S

for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233748

Device Name
CIARTIC Move (VB10)

Indications for Use *(Describe)*
The CIARTIC Move is a mobile X-ray system designed to provide X-ray imaging of the anatomical structures of patients during clinical applications. Clinical applications may include but are not limited to interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care, and emergency room procedures. The patient population may include pediatric patients.

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: CIARTIC Move (VB10)

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: February 14, 2024

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

   Importer / Distributor:
   Siemens Medical Systems USA, Inc.
   40 Liberty Boulevard
   Malvern, PA 19355
   Establishment Registration Number: 2240869

   Manufacturing Site:
   Siemens Healthineers AG
   ROENTGENSTRASSE 19-21
   95478 KEMNATH, Germany
   Establishment Registration Number: 3002466018

2. **Contact Person:**

   Patricia D. Jones
   Regulatory Affairs Specialist
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard
   Malvern, PA 19355
   Phone: (678) 575-8832
   Email: patricia.jones@siemens-healthineers.com

3. **Device Name and Classification:**

Trade Name:	CIARTIC Move (VB10)
Classification Name:	Image-Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, JAA, OXO

4. **Legally Marketed Predicate Device**

Trade Name:	Cios Spin (VA30)
510(k) Clearance	K210054
Clearance Date	February 5, 2021
Classification Name:	Image-intensified fluoroscopic X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650

Device Class:	Class II
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO
Total Product Life Cycle:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any applicable issues.

Reference Device	
Trade Name:	Excelsius3D™
510(k) Clearance	K210912
Clearance Date	February 5, 2021
Classification Name:	Image-intensified fluoroscopic X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO

5. Device Description:

The CIARTIC Move is a mobile fluoroscopy C-arm x-ray system designed for the surgical environment. CIARTIC Move provides comprehensive image acquisition modes to support orthopedic and vascular procedures.

The CIARTIC Move consists of two major components:
A. The C-arm with an X-ray source on one side and the flat panel detector on the opposite side. The c-arm can be angulated in both planes and lifted vertically, shifted to the side and moved forward/ backward by an operator. All axes are motorized.

B. The monitor trolley provides image processing, review, and patient data entry. The monitor trolley supports an optional hardcopy printer and navigational equipment. The trolley is connected to a mains power outlet or an optional data network.

The following modifications were made to the Predicate Device the Cios Spin Mobile X-ray System cleared under Premarket Notification K210054 on February 5, 2021. Siemens Medical Solutions USA, Inc. submits this Traditional 510(k) to request clearance for the Subject Device the CIARTIC Move VB10. The following modifications are incorporated in the Predicate Device to create the Subject Device, for which Siemens is seeking 510(k) clearance:

Table 1: Subject Device Modifications

Software / Hardware changes specific to New System Software VB10A
1. Updated system Software from VA30G to VB10A
A. Updated Park Assist
B. Updated Position Assist
C. Updated Smart Control
D. Updated ISO Assist

Software / Hardware changes specific to New System Software VB10A
E. Updated Touch Sensitive Handle on (C-Arm Mobile Base) with control panel for moving, transporting, braking, and positioning C-arm Mobile Base.
F. Updated Touch Sensitive handles on Flat Detector (FD) by adding additional controls on the FP control panel for up/ down, orbital, and angular movement of C-arm and C-Arm Mobile Base itself
G. Updated Display to 32" Touch Sensitive
H. Updated Touch User Interface (TUI).
I. Added Collision Detection and Avoidance to the CIARTIC Move System
J. Added a Movement indicator to Monitor Trolley
K. Updated Retina 3D for optional Field of View (FOV) 25cm x 25cm x 16cm
L. Updated the C-Arm Mobile Base with 4 motorized Holonomic wheels, which allows the C-Arm Mobile Base to move straight ahead, sideways, diagonally, and 360o rotation
M. Updated Collimator
2. Updated PC
3. Revised Indications for Use Statement
4. Product Claims List
5. Updated 510(k) information for the Primary Predicate Device

6. Indications for Use:

The CIARTIC Move is a mobile X-ray system designed to provide X-ray imaging of the anatomical structures of patients during clinical applications. Clinical applications may include but are not limited to interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care, and emergency room procedures. The patient population may include pediatric patients.

7. Substantial Equivalence:

The CIARTIC Move (VB10A) is within the same classification regulation with the same indications for use as the legally marketed predicate listed in **Table 2.** below:

Table 2: Predicate Device Comparable Properties for Subject Device Modifications:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate Device	K210054	2/5/2021	• Indications for use • Image processing • Mechanical design • Software • Collimator • PC hardware • Interactive User Touch Control • Display • C-Arm Mobile Base • Monitor Trolley
Cios Spin (VA30) Siemens			
Reference Device	K210912	08/12/2021	• Holonomic Wheel
Excelsius3D™ Globus Medical Inc.			

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The Indications for Use Statement is exactly the same as the cleared Predicate Device "Cios Spin" with the exception of the trade name of the Subject Device "CIARTIC Move."

The CIARTIC Move with system software version VB10A contains the following modifications that were made to the predicate device. Provided in **Table 3** is a summary of the comparison of Technological Characteristics to the Predicate Device. The following technological differences exist between the subject and predicate devices:

Table 3: Summary of Comparison of Technological Characteristics

Subject Device CIARTIC Move (VB10A) System Modifications		Predicate Device Cios Spin (VA30) K210054	Comparison Results
1.	Software update from VA30 to VB10A to support the following new hardware and software features	VA30 System Software	**Modified:** System software VA30 to VB10A which includes the following software and hardware changes. All modifications differences between the Subject Device and Predicate Device Software and Hardware Functions were evaluated in software VB10A. System Software modifications listed in 1A-2 conform to the "Guidance for the Content of Premarket Submission for Device Software Functions." Software testing which identifies all testing pertinent to each modification is provided. These software and hardware changes do not raise any new risks or issues regarding the safety or effectiveness of the device. All test results met all acceptance criteria.
	A. Updated Park Assist	The system can be moved to parking position manually.	
	B. Updated Position Assist	C-arm positions can be stored (angular/orbital angles); up to 3 positions.	
	C. Updated Smart Control	Radiation release and image saving were possible with hand switch.	
	D. Updated ISO Assist	The functionality of ISO Assist was possible only when the angular/ orbital position of the C-arm is 0°.	
	E. Updated Touch Sensitive Handle on C-Arm Mobile Base with control panel for moving, transporting, braking, and positioning C-arm Mobile Base.	Handles on chassis (not touch-sensitive) for manual movement.	
	F. Updated Touch Sensitive handles on FD by adding additional controls on the FD control panel for up/ down, orbital, and angular movement of C-arm and C-Arm Mobile Base.	Handle (FD) (not touch-sensitive) for manual movement.	
	G. Updated Display to 32" Touch Sensitive	2 smaller 19" displays	
	H. Updated Touch User Interfaces on the C-arm system control panel (CCP), Trolley Control panel (TCP) on monitor trolley, and optional remote control panel (RCP) that can be placed on an	Smaller 12.1" resistive touch technology, resolution of 1280 x 800 pixels for all TUIs	

Subject Device CIARTIC Move (VB10A) System Modifications		Predicate Device Cios Spin (VA30) K210054	Comparison Results
	optional cart close to the patient table.		
	I. Added Collision Detection and Avoidance to the CIARTIC Move System	Non existent. The user has to take care that the collision does not occur.	
	J. Added a Movement indicator to Monitor Trolley	Rudimentary movement indicator to indicate the deviation from target position (<1°, <5°,>5°)	
	K. Updated Retina 3D for optional enlarged Field of View (FOV) 25cm x 25cm x 16cm.	Retina 3D image chain with 3D reconstruction mode 16 cm x 16 cm x 16cm	
	L. Updated the C-Arm Mobile Base with 4 motorized Holonomic wheels, which allows the C-Arm Mobile Base to move straight ahead, sideways, diagonally, and 360° rotation.	The system can be moved manually with non-motorized wheels.	
	M. Updated Collimator	Collimator	
2.	Updated PC	The PC HW is W550 from Fujitsu with the following features: • CELSIUS W550power-L • Core i3-6100 • Memory 8GB DDR4-2133 ECC • HDD SATA III 2000GB 7.2k BC • Fixed Slot and SATA-Port for HDD and ODD • PCI-Boards and card brackets • DVD SuperMulti SATA • Input: 230 Vac	
3.	Revised the Indications for Use Statement	Indications for Use Statement	**Modified:** Added the Subject Device Trade name: "CIARTIC Move."
4.	Product Claims List is provided		
5.	Updated 510(k) information for the Primary Predicate Device is provided		

9. Nonclinical Performance Testing:

During product development the following non-clinical testing was conducted on the listed modifications provided in **Table 4** in support of the substantial equivalence determination.

Table 4: Conducted Non-Clinical Testing

The following non-clinical testing was conducted on the listed modifications and relied on:		
Modification	**Conducted Test**	**Test Results**
Software update from VA30 to VB10A to support the following new hardware and software features	Software functional, verification, and System validation testing were conducted for Software version VB10A.	Passed
Updated Park Assist Updated Position Assist	Testing was conducted with the user temporarily parking the Mobile C-arm Base Unit to a convenient position in the OR, away from the table, and restoring the previous position automatically.	Passed
Updated Smart Control	Testing was conducted with the user positioning the system to the intended anatomical region via wired and wireless smart controls.	Passed
Updated ISO Assist	Testing was conducted with the user to adjusting the distance (patient-to-detector) while maintaining the iso-center. The purpose to change the distance between flat detector and patient may be to zoom in or out, or to gain more operating space between detector and patient.	Passed
Updated Touch Sensitive Handle on C-Arm Mobile Base with control panel for moving, transporting, braking, and positioning C-arm Mobile Base. Updated Touch Sensitive handles on FD by adding additional controls on the FD control panel for up/ down, orbital, and angular movement of C-arm and C-Arm Mobile Base.	Testing was conducted with the user when preparing the system for the next intervention and when driving the mobile C-arm base unit to the intended anatomical region at the OR table.	Passed
Updated Display to 32” Touch Sensitive	Testing was conducted to check at system integration level the following aspects: the monitor resolution and refresh rate, the monitor touch function, the mechanical interface of the monitor mount to the monitor trolley.	Passed
Updated Touch User Interfaces on the C-arm system control panel (CCP), Trolley Control panel (TCP) on monitor trolley, and optional remote control panel (RCP) that can be placed on an optional cart close to the patient table.	Testing was conducted to check steps surgeons, and the OR staff perform during a fracture reduction with joint involvement and during a pedicle screw placement.	Passed
Added Collision Detection and Avoidance to the CIARTIC Move System	Testing was conducted to check OR staff performing when transporting the mobile C-arm base unit to the intended equipment storage area. Testing focused on checking the operator’s manual risk mitigations, correctness of system behavior during collision detection and avoidance, and correctness of wheel motor torque limits upon collision detection.	Passed
Added a Movement indicator to Monitor Trolley	Testing was conducted to focus on checking correctness of the movement indicator.	Passed

The following non-clinical testing was conducted on the listed modifications and relied on:		
Modification	**Conducted Test**	**Test Results**
Updated Retina 3D for optional enlarged Field of View (FOV) 25cm x 25cm x 16cm	Testing was conducted to focus on checking that a defined cylinder phantom can be completely sampled and reconstructed for both regular and enlarged volume. The objective of the test is to demonstrate that the enlarged volume of the CIARTIC Move can be used for navigation based on a universal navigation interface.	Passed
Updated the C-Arm Mobile Base with 4 motorized Holonomic wheels, which allows the C-Arm Mobile Base to move straight ahead, sideways, diagonally, and 360º rotation.	Testing was conducted to focus on checking the following functions: 1. The mobile C-arm base unit can be moved in all possible directions by a motor as well as braking in different situations. 2. The movement platform ensures stability against tilting, also on uneven floor. 3. The cable deflectors can deflect cables lying on the floor when the mobile C-arm base unit is moved.	Passed
Updated collimator	Testing was conducted to focus on checking the following functions: 1. Collimator initialization and general behavior 2. Collimator leaves are not visible in the image for all C-arm positions. 3. Rotation velocity of the rotation collimator 4. Open/close behavior, home positioning, coupling and decoupling of 1st Slot Collimator 5. Open/close timing, minimal opening and user formats of the rectangle collimator 6. Rectangle collimator can limit the X-ray beam to the active image format in overview, zoom1 and zoom2	Passed

The Siemens CIARTIC Move (VB10A) has been tested to meet the requirements for conformity to multiple industry standards. Performance testing confirmed, that the Siemens CIARTIC Move (VB10A) complies with the following 21 CFR Federal Performance Standards.

Code of Federal Regulations Title 21 Subchapter J- Radiological Health, applicable sections include:

- 1020.30 Diagnostic X-Ray System and their major component
- 1020.32 Fluoroscopic Equipment
- 1040.10 Laser products

The CIARTIC Move (VB10A) was certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance, and Electromagnetic Compatibility:

- AAMI ANSI 60601-1-2:2014 [Including AMD 1:2021]
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
- IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION

- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
- IEC 60825-1:2014
- IEC 62304:2015
- IEC 60601-2-28:2017
- IEC 60601-2-43:2019
- IEC 60601-2-54:2018
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- ISO 14971:2019
- NEMA ps3.1:2022
- ANSI UL 2900-1:2023
- ANSI UL 2900-2-1:2023

Table 5: FDA Guidance Documents

FDA Guidance Document and Effective Date	
1.	Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k)** **Document issued on October 2, 2017**
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s** **Document issued on September 13, 2019**
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s** **Document issued on September 13, 2019**
4.	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**
5.	Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** **Document Issued on July 28, 2014**
6.	Guidance for Industry and FDA Staff: **Guidance for the Submission Of 510(k)'s for Solid State X-ray Imaging Devices** **Document issued on September 1, 2016**
7.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices** **Document issued on September 27, 2019**
8.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Device Software Functions** **Document issued on June 14, 2023**
9.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices**. **Document issued February 3, 2016**
10.	Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications.** **Document issued on November 28, 2017**
11.	Guidance for Industry and FDA Staff: **Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.** **Document issued on October 2, 2014**
12.	Guidance for Industry and FDA Staff: **Appropriate Use of Voluntary Consensus Standards in Premarket Submission for Medical Devices** Document issued on September 14, 2018
13.	Guidance for Industry and FDA Staff: **Medical Device Accessories - Describing Accessories and Classification Pathways** **Document issued on December 20, 2017**

FDA Guidance Document and Effective Date	
14.	Guidance for Industry and FDA Staff: **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions Document issued on December 20, 2019**
15.	Guidance for Industry and FDA Staff: **Electronic Submission Template for Medical Device 510(k) Submission** Document issued on October 2, 2023

The modifications described in this Premarket Notification are supported with verification and validation testing.

Verification and Validation:
Software Documentation for a **Basic Documentation** Level software per FDA's Guidance Document "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance for medical devices containing software. Non-clinical tests were conducted on the Subject Device CIARTIC Move with software version VB10A during product development.

The Risk analysis was completed, and risk control was implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Bench testing in the form of Unit, Subsystem, and System Integration testing was performed to evaluate the performance and functionality of the new features, hardware, and software updates. All testable requirements in the Engineering Requirements Specifications keys, Subsystem Requirements Specifications keys, and the Risk Management Hazard keys have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process. The software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans.

Electrical safety and EMC testing were conducted on the CIARTIC Move, consisting of the acquisition unit (C-arm system) and the image processing and display station. The system complies with the IEC 60601-1, IEC 60601- 2-43, and IEC 60601-2-54 standards for safety and the IEC 60601-1-2 standard for EMC.

The CIARTIC Move with software (VB10A) was tested and found to be safe and effective for intended users, uses, and use environments through the design control verification and validation process. The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual and in clinical use tests with customer reports and feedback forms. Customer employees are adequately trained in the use of this equipment.

Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse, or denial of use, or the

unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section is the required cybersecurity information.

Clinical Study Title:
A prospective evaluation of clinical performance and safety of CIARTIC Move in comparison to Cios Spin in terms of timesaving in different clinical procedures were conducted.

Objective:
The primary objective of the study was to evaluate the intraoperative imaging time saving (IIT) of CIARTIC Move VB10 compared to Cios Spin VA30. Procedural times, number of images, and dose area product were evaluated as secondary objectives.

Study Design:
Cross-sectional two-arm, controlled, open-label, mono-center, exploratory study with human specimens (body donations).

Primary Endpoint:
The primary endpoint was the time difference in seconds of the duration of the intraoperative imaging. (Intraoperative Imaging Time IIT) performed under imaging control with Cios Spin VA30 compared to CIARTIC Move VB10.

Total Intraoperative imaging time in sec defined as sum of all park-to-image-times (PTI) and image-to-park times (IPT) per procedure. IIT Cios Spin VA30J – IIT CIARTIC Move VB10= Δ IIT The IIT was evaluated for each surgery, spine and radius separately. In addition, the total intraoperative imaging time to capture the 5 standard projections (AP, Lateral, Inlet, outlet, obturatory) at the pelvis was determined.

Clinical Report Summary:
The purpose of the study was to evaluate the CIARTIC Move VB10 compared to the Cios Spin VA30J in regard to intraoperative imaging time saving and number of images and other parameters. The study was conducted on human body donations in order to avoid radiation exposure to living humans.

The clinical data demonstrate that the CIARTIC Move VB10 performs comparably to the predicate device that is currently marketed for the same intended use.

Clinical and Non-Clinical Summary:
Performance tests were conducted to evaluate the functionality of the CIARTIC Move (VB10A). These tests have been performed to assess the functionality of the Subject Device. The results of all conducted testing and clinical assessments were found acceptable and did not raise any new issues of safety or effectiveness.

10. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device safely and effectively.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing. To minimize electrical and mechanical hazards, Siemens adheres to recognized and established industry practices, and all equipment is subject to final performance testing. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluation and post-processing of X-ray images.

11. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrate that the CIARTIC Move (VB10A) System acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data, and software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Devices that is currently marketed for the same intended use.