October 30, 2018

Siemens Medical Solutions USA, Inc.
Patricia D. Jones
Senior Regulatory Affairs Technical Specialist
40 Liberty Boulevard 65-1A
Malvern, Pennsylvania 19355

Re: K181550
Trade/Device Name: Cios Spin
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO
Dated: June 11, 2018
Received: June 13, 2018

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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'hara -S

Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300226759, cn=Michael D. O'hara -S
Date: 2018.10.30 09:01:21 -04'00'

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181550

Device Name
Cios Spin

Indications for Use *(Describe)*
The Cios Spin is a mobile X-Ray system designed to provide X-ray imaging of the anatomical structures of patient 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: Cios Spin (VA30)

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared: October 2, 2018

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, 65-1A
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site/Manufacturer:
SIEMENS AG Sector Healthcare
Röntgenstrasse 19 – 21
D-95478 Kemnath, Germany
Establishment Registration Number: 3002466018

2. Contact Person:

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Phone: (610) 448-6474
Email: patricia.d.jones@siemens-healthineers.com

3. Device Name and Classification:

Trade Name:	Cios Spin
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, OXO

4. Legally Marketed Primary Predicate Device

Trade Name:	Cios Alpha
510(k) Clearance #:	K132094

Clearance Date:	March 11, 2014
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, OXO
Recall Information:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

Legally Marketed Secondary Predicate Device

Trade Name:	ARTIS pheno (VE10)
510(k) Clearance #:	K163286
Clearance Date:	March 9, 2017
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA
Recall Information:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

Legally Marketed Secondary Predicate Device

Trade Name:	Arcadis Orbic (3D)
510(k) Clearance #:	K042793
Clearance Date:	October 29, 2004
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, OXO, JAA
Recall Information:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

Legally Marketed Secondary Predicate Device

Trade Name:	Arcadis Avantic
510(k) Clearance #:	K051133
Clearance Date:	June 1, 2005
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OXO
Recall Information:	No Recalls

5. Device Description:

The Cios Spin mobile fluoroscopic C-arm X-ray System designed for the surgical environment. The Cios Spin provides comprehensive image acquisition modes to support orthopedic and vascular procedures. The system consists of two major components:

a) The C-arm with X-ray source on one side and the flat panel detector on the opposite side. The c-arm can be angulated in both planes and be lifted vertically, shifted to the side and move forward/backward by an operator.

b) The second unit is the image display station with a moveable trolley for the image processing and storage system, image display and documentation. Both units are connected to each other with a cable.

The main unit is connected to the main power outlet and the trolley is connected to a data network.

The following modifications were made to the predicate device the Cios Alpha. Siemens Medical Solutions USA, Inc. submits this Traditional 510(k) to request clearance for the Subject Device the Cios Spin for the following device modification made to the Predicate Device (Cios Alpha (VA10).

Proposed Device Modifications:

1) Updated the Indications for Use Statement to include the Subject Device Name: "Cios Spin"
2) New Software VA30 due to new functionality
   a) New Flat Panel Detector Model **(Software & Hardware)**
   b) New Algorithm for Metal Artifact Reduction **(Software)**
   c) New Retina 3D **(Software)**
   d) Screw Scout **(Software)**
   e) Target Pointer **(Software)**
   f) Cios Open Apps **(Hardware & Software**
   g) High Power 3D **(Hardware & Software)**
   h) Easy 3D **(Software)**

3) Mounted Remote Control Unit on Cart/Trolley **(Hardware)**
4) New Digital Cine Mode (DCM) 3D **(Software)**
5) New Green Color for Laser Aim **(Hardware)**
6) Optional Navilink 3D **(3rd Party Component)**
7) Anti-microbial Coating on C-Arm and Trolley **(Hardware)** w/ cleaning instructions
8) Optional Wireless or Wired Footswitch **(Software & Hardware)**
9) Proposed Product Claims List

The Subject Device Cios Spin (VA30) is within the same classification regulation with the same indication for use as the predicate devices.

6. Indications for Use:

The Cios Spin is a mobile X-Ray system designed to provide X-ray imaging of the anatomical structures of patient 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 Cios Spin (VA30) is substantially equivalent to the commercially available primary predicate device Siemens Cios Alpha (VA10), cleared 11/03/2014 with K132094.

Indications for use remain unchanged the technology is similar. The predicate Flat Panel detector (a-Si technology) has been replaced by a CMOS Flat Panel detector. X-ray generation and control used with the Cios Spin is similar to the technology used with the primary predicate device Cios Alpha. **Table 1** provides primary and secondary Predicate Devices comparable information.

Table 1: Primary and Secondary Comparable Properties

Predicate Device(s) Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Siemens **Primary Predicate:** Cios Alpha **Product Codes**: OWB, OXO	K132094	March 11, 2014	-Indications for Use- -System for Image Acquisition -Post processing Software -Detector
Siemens **Secondary Predicate**: ARTIS pheno **Product Codes:** OWB, JAA	K163286	March 09, 2017	-Anti-Microbial Coating -Ant-Microbial Coating Claims -Cleaning Instructions
Siemens **Primary Predicate:** ARCADIS Avantic **Product Codes**: OXO	K051133	June 1, 2005	-Digital Cine Mode (DCM)
Siemens **Secondary Predicate:** ARCADIS	K042793	October 29, 2004	-3D functionality

Predicate Device(s) Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Orbic 3D **Product Codes:** OWB, OXO, JAA			-C-arm Range
Reference 510(k) Information			
Siemens **Reference 510(k):** *syngo* Application Software (VA20) **Product Codes:** LLZ	K170747	June 9, 2017	-Metal Artifact Reduction Software
ZIEHM IMAGING GMBH **Reference 510(k):** ZIEHM Vision RFD **Product Codes:** OWB, OXO JAA	K132904	December 12, 2013	-Detector Information
ZIEHM IMAGING GMBH **Reference 510(k):** Solo FD Mobile Imaging System **Product Codes:** OWB, OXO JAA	K161976	October 6, 2016	-Detector Information

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

The Cios Spin (VA30) is substantially equivalent to the commercially available Siemens Cios Alpha (VA10), cleared 03/11/2014 with K132094.

The Indication for use remains unchanged and technology and design of the Cios Spin (VA30) is based on the Cios Alpha (VA10). The predicate Flat Panel detector (a-Si technology) has been replaced by a CMOS Flat Panel detector and an optional wireless footswitch.

An anti-microbial coating is added to the trolley and C-Arm which are components of the Cios Spin (VA30). The anti-microbial coating and associated claims were cleared in the secondary Predicate Device the ARTIS pheno (K163286) on March 9, 2017.

Table 2 provides comparison of the Subject Device modifications to the Predicate Devices.

Table 2: Comparison of Technological Characteristics

Modifications	Subject Device Cios Spin (VA30)	Primary Predicate Device Cios Alpha (VA10) K132094	Secondary Predicate Device ARTIS pheno (VE10) K163286	Comparison Results
1. IFU Statement	Same IFU Statement – Changed Name to Cios Spin	Same IFU cleared in 510(k)	N/A	Same except for Name Change from Cios Alpha to Cios Spin. The intended use and IFU of the device remains the same.
2. System Software	Software Version VA30	Software Version VA10	N/A	VA30 was developed to support identified modifications (a-f). Testing requirements are acceptable per Software and SSIX guidance requirements.
	a) CMOS technology Detector (**Software & Hardware)**	a-Si technology Detector	N/A	Equivalent image quality does not raise any new issues of safety of effectiveness. Non-clinical testing was conducted and is acceptable per SSIX Guidance Document
	b) Algorithm for Metal Reduction (**Software)** mportant diagnostic information can be obscured by metal artifacts. Metal Artifact Reduction improves the image quality by reducing these artifacts	N/A	N/A	**Reference 510(k)** *syngo* Application Software VD20B (K170747) contains a Metal Reduction software feature that is comparable to the Metal Reduction Software feature in the VA30 software for the Cios Spin, the algorithms is unchanged.
	c) Retina 3D **(Software)** provides precise 3D visualization of fine structures in exceptional image quality lets you confidently see and evaluate anatomical structures, implants, screws, and devices. 3D images reconstruction from 2D images.	N/a	Yes	Non-clinical Summaries for Retina 3D, Screw Scout, Larger C-Arm range, Target Pointer, Open Apps non-clinical testing and Software Verification /validation testing was conducted and is acceptable per Software Guidance document. The Retina 3D Feature has the same reconstruction algorithm as the predicate ARTIS Pheno.

Modifications	Subject Device Cios Spin (VA30)	Primary Predicate Device Cios Alpha (VA10) K132094	Secondary Predicate Device ARTIS pheno (VE10) K163286	Comparison Results
	The 2D images are acquired during an orbital sweep.			
	d) Screw Scout **(Software)** Screw Scout automatically localizes screws and prepares the optimal view of any screw in the 3D dataset.	N/A	N/A	
	e) Target Pointer **(Software)** delivers a trajectory that helps surgeons to optimally position k-wires or other devices and ultimately save time.	N/A	N/A	
	f). Cios Open Apps – **(Hardware & Software)** This feature allows the user to use different external applications in a separate integrated PC (in the trolley).	N/A	N/A	
	g) High Power 3D **(Software)**	N/A	N/A	Does not raise any new issues of safety of effectiveness per Software Guidance.
	h) Easy 3D **(Software)**	N/A	N/A	Does not raise any new issues of safety of effectiveness per Software Guidance.
3. Mounted Remote Control Unit on Cart/Trolley	Mounted Remote Control Unit on Cart	N/A	N/A	Does not raise any new issues of safety of effectiveness per verification and validation testing.
4. Digital Cine Mode	Digital Cine Mode (DCM) 3D	N/A	**Secondary Predicate Device Arcadis Avantic K051133**	Same except for being able to view in 3D. Feature does not raise any new safety or effectiveness issues

Modifications	Subject Device Cios Spin (VA30)	Primary Predicate Device Cios Alpha (VA10) K132094	Secondary Predicate Device ARTIS pheno (VE10) K163286	Comparison Results
			Digital Cine Mode	per verification and validation testing.
5. Laser Aiming Beam	Green Color Laser Aiming Beam	Red color Aiming Beam	N/A	New Green color for laser Aiming Beam does not impact the Safety or the effectiveness of the feature.
6. NaviLink 2D Intergrated 2D navigation interface	Optional NaviLink 3D integration allows connection to an external Navigation system. NaviLink 3D is a digital interface to connect with certified navigation systems. It automatically transfers 3D datasets to the navigation systems for combined use of image guided and navigated surgery.	NaviLink 2D Intergrated 2D navigation interface	N/A	Similar functionality. 3D integration does not raise any new issues of safety and effectiveness
7. Anti-Microbial Coating w/Cleaning Instructions	Optional Anti-Microbial coating on C-Arm and Trolley	N/A	Optional Anti-Microbial coating on C-Arm and Trolley	Same
8. Footswitch	Wired footswitch	Wired Footswitch	N/A	Same
	Optional Wireless footswitch	N/A	N/A	Optional wireless footswitch with same functionality like wired footswitch. Wireless version does not raise any new safety or effectiveness issues. Tested per Wireless Guidance.
9. Proposed Product Claims List				

9. Non-clinical Performance Testing:

The Siemens Cios Spin has been tested to meet the requirements for conformity to multiple industry standards. Performance testing confirmed, that the Siemens Cios Spin complies with the following 21 CFR Federal Performance Standards:

1020.30 Diagnostic X-Ray Systems and their major components

1020.32 Fluoroscopic equipment

1040.10 Laser products

Siemens conforms to the following relevant voluntary FDA Recognized Consensus Standards as listed in the table below: The Cios Spin is certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following voluntary standards listed in **Table 3** below:

Table 3: Conformance Standards

Standards Development Organization Reference Number and Date		Standards Development Organization Reference Number and Date	
1	AAMI ANSI ES60601-1:2005/ (R)2012	7	IEC 60601-2-28:2010
2	AMI ANSI IEC 60601-1-2:2014	8	IEC 60601-2-43:2017 (recognized 2010)
3	IEC 60601-1-3:2013	9	IEC 60601-2-54:2009/A1:2015
4	IEC 60601-1-6:2010/A1:2013	10	ISO 14971:2007
5	IEC 60825-1:2014 (recognized: 2007)	11	IEC 62366-1:2015/Cor1:2016
6	IEC 62304:2015		

Table 4: FDA Guidance Documents

FDA Guidance Documents 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 January 30, 2018
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff** Document issued on August 12, 2005
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 the Content of Premarket Submission for Software in Medical Devices** Document issued on May 11, 2005
8.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices**

FDA Guidance Documents and Effective Date	
	Document issued on September 9, 1999
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: **Radio Frequency Wireless Technology in Medical Device** Document issued on August 14, 2007.
13.	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

Verification and Validation:

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the Subject Device Cios Spin software version VA30 during product development.

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

The Cios Spin software VA30 was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. All new software functions present in the Subject Device (Metal Artifact Reduction, Retina 3D, Screw Scout, Target Pointer, High power 3D, and Easy 3D) have been validated through detailed software testing and it was founded they worked as intended. 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 report and feedback form. 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.

Additional engineering bench testing was performed including: the non-clinical testing identified in the guidance for submission of 510(k) s for Solid State X-Ray Imaging Devices (SSXI); demonstration of system performance; and an imaging performance evaluation. X-ray Imaging Devices- Laboratory Image Quality and Dose Assessment, Tests and Standards were performed with acceptable results.

With regards to the flat panel detector (SSXI), test documentation provided in this submission demonstrates compliance of the Cios Spin to "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices". The evaluation includes but is not limited to the following performance metrics identified in the SSXI guidance, showing comparable or better performance of the Cios Spin to its predicate and referenced devices. Provided in **Table 5** for detector is equivalent comparative information.

Table 5: SSXI Metrics

SSXI Metrics	**Cios Spin Performance compared to Predicate Device and Reference Devices**			
	Subject Device Cios Spin (VA30)	**Pr11edicate Device Cios Alpha (VA10) K132094**	**Reference Device Ziehm Vision RFD K132904**	**Reference Device Ziehm Solo FD K161976**
Imaging Modes	Pulsed fluoroscopy Single images	Pulsed fluoroscopy Single images	Pulsed Fluoroscopy Digital Spot	Pulsed Fluoroscopy Digital Spot
DQE	72%	76%	Information Not Available	70%
Dynamic Range	96dB	94dB	Information Not Available	Equivalent
Modulation Transfer Function (MTF)	58% at 1 lpmm large)	55% at 1 Lp/mm	Information Not Available	4lp/mm
Digitization depth	16 bit	16 bit	16 bit	16 bit
Pixel Pitch	152 µm	194µm	194 µm	100 µm
Field of View	FPD: * 30 cm x 30 cm * 20 cm x 20 cm	Small FPD: * 20 cm x 20 cm * 15 cm x 15 cm * 10 cm x 10 cm Large FPD: * 30 cm x 30 cm * 20 cm x 20 cm	FPD 20 cm: • 20 cm • 15 cm • 10 cm	FPD 20 cm: • 20 cm • 15 cm • 10 cm

Because Cios Spin´ new flat panel detector does not change the system's intended use and represent equivalent technological characteristics, clinical images are not required. Also, Siemens has demonstrated that clinical images are not needed to demonstrate that the device is as safe and as effective as the predicate and reference devices.

Summary:
Performance tests were conduct to test the functionality of the Cios Spin (VA30). These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing and clinical assessments were found acceptable and do 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 in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Cios Spin is continually monitored and if an error occurs, the system functions will be blocked and an error message will be displayed.

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 practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray images.

11. Conclusion as to Substantial Equivalence:

The predicate devices were also cleared based on the non-clinical supportive information and clinical images and data per Guidance documents. Similar non-clinical test results demonstrate that the Cios Spin software version VA30 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 Devices are as safe and effective when compared to the Predicate Devices that is currently marketed for the same intended use.