DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Volcano Corporation
% Ms. Elaine Alan
Regulatory Affairs Specialist
3721 Valley Centre Drive, Suite 500
SAN DIEGO CA 92130

October 5, 2017

Re: K172574
Trade/Device Name: SyncVision System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB
Dated: August 25, 2017
Received: August 28, 2017

Dear Ms. Alan:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert 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)*
K172574

Device Name
SyncVision System

Indications for Use *(Describe)*

The SyncVision System is an image acquisition and processing system. It is indicated for use as follows:
- To provide quantitative information regarding the calculated dimensions of arterial segments.
- To enhance visualization of the stent deployment region.
- To be used in-procedure in the catheterization lab and off-line for post-procedural analysis.
- To obtain a co-registration of an angiographic x-ray image and IVUS images.
- To obtain a co-registration of an angiographic x-ray image and intravascular blood pressure values.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: September 29, 2017

CONTACT/ SUBMITTER: Elaine Alan
Regulatory Affairs Specialist
Volcano Corporation
3721 Valley Center Dr. Tel: 858-764-1281
San Diego, CA 92130 Email: ealan@volcanocorp.com

Manufacturer: Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670
Establishment Registration Number: 2939520

DEVICE:

Trade Name:	SyncVision System
Common Name**:**	SyncVision System
Classification Name:	Interventional fluoroscopic x-ray system
Classification:	21 CFR 892.1650
Device Class ：	Class II
Product Code:	OWB
Panel:	Radiology

PREDICATE DEVICE: SyncVision System, K161756

DEVICE DESCRIPTION:
The current standard procedure in the catheterization laboratory (cath lab) for utilizing x-ray and IVUS image streams calls for referencing the native x-ray, IVUS and FFR/iFR imaging and displayed value streams of the patient's vasculature separately on different displays or monitor. This configuration requires the physician, usually an interventional cardiologist, to estimate an identical location on the patient's vasculature location on both the x-ray, IVUS image streams, and FFR/iFR displayed value streams visually on adjacent windows on the same display.

The SyncVision System (System) is displayed on a monitor that is situated next to the native x-ray, IVUS and FFR/iFR imaging and displayed value streams either in the cath lab or in the control room. The System provides a means to view the angiographic, IVUS, and FFR/iFR values on a single display and automates the manual registration processes performed by the physician.

The objective of the SyncVision System is to optimize and facilitate trans-catheter cardiovascular interventions by means of automated on-line image processing. The current focus of the SyncVision System is on trans-catheter diagnostic and therapeutic interventions performed on the heart and the blood vessels directly connected to it.

The SyncVision System's core component is an image acquisition and processing workstation situated in the coronary catheterization control room. The System also includes additional components such as a procedure room joystick, control room monitor, keyboard and mouse, medical grade isolation transformer along with site-specific cables and video equipment. Cables also connect the workstation to an existing output monitor (not supplied with the System) situated in the procedure room and provide the user in the procedure room with the visual output of the System side-by-side to the existing displays.

The SyncVision System intends to capture the fluoroscopic image stream on line and perform the following functions for the purpose of assisting the interventional cardiologist in visualizing and quantitating the information resulting from images produced by the existing imaging modalities:

- During lesion evaluation: Angiogram selection, quantitative coronary measurements (lesion diameters, length, and stenosis percentage), vessel region enhancement and vessel region stabilization are performed instantly and on line.
- During device positioning, deployment and post-deployment: An on-line image stream, that is enhanced and stabilized, is displayed side-by-side with the existing fluoroscopic image stream.
- Import and display of IVUS images, leading to a joint display of images acquired by X-Ray and IVUS images corresponding to same selected luminal locations or segments (also known as IVUS Co-registration).
- Import and display of Physiological values, leading to a joint display of images acquired by X-Ray and Physiological values corresponding to same selected luminal locations or segments (also known as Physiological Co-registration).

The Co-Registration is an automation of a manual workflow process used by interventional cardiologists today. The manual procedure in the cath lab for utilizing x-ray and IVUS image

streams calls for referencing the native x-ray and IVUS image streams of the patient's vasculature separately on different displays. This configuration requires the cardiologist to estimate an identical location on the patient's vasculature on the two native image streams (x-ray and IVUS) on two separate displays. The SyncVision System automates this process by providing an option to display an identical anatomical location on both the x-ray and IVUS image streams automatically on adjacent windows on the same display.

INDICATIONS FOR USE:
The SyncVision System is an image acquisition and processing system. It is indicated for use as follows:

- To provide quantitative information regarding the calculated dimensions of arterial segments.
- To enhance visualization of the stent deployment region.
- To be used in-procedure in the catheterization lab and off-line for post-procedural analysis.
- To obtain a co-registration of an angiographic x-ray image and IVUS images.
- To obtain a co-registration of an angiographic x-ray image and intravascular blood pressure values.

The primary modifications are to software of the SyncVision Software to enhance the Physiology Co-Registration capability, which correlates between physiological values obtained from Volcano's pressure wire pullback (both iFR and FFR calculations) and their respective locations on a selected angiographic image. There are also administrative, infrastructure, and service modifications. The primary modifications of the new device compared to the predicate device are provided in the Modification Comparison table below.

Modification Comparison

Proposed Modification	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comments
Automated Roadmap: Automation of the Pathway indication phase in the Physiology Co-Registration workflow	During co-registration set-up, after performing an angiogram and the pressure wire pullback, the system selects the angiogram frame to be used then the user manually indicates the pathway to be used for the physiology pullback.	During co-registration set-up, after performing an angiogram and the pressure wire pullback, the system selects the angiogram frame and automatically calculates the pathway to be used for co-registration.	Eliminates the need to perform the manual processes. The user may still elect to edit or manually draw the pathway. A new Edit Pathway button has been added to the GUI for this function.
Co-registration region indication represented by white triangle at the proximal & distal ends of the co-registration region.	During co-registration set-up, after performing an angiogram and the pressure wire pullback, the area in which the pullback was performed is not indicated.	During co-registration set-up, after performing an angiogram and the pressure wire pullback, the area in which the pullback was performed is marked	Aids the user in visualizing the area of interest of the vessel that was used for Co-Registration.

Proposed Modification	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comments
		by white triangles at the beginning and end of the pullback.	
Display of Measurement Points - Display white dots on the roadmap, representing the iFR measurement location.	Display of 'white dots' not available. In the current system to view a single measured point the user clicks along the Roadmap and the cursor indicates the measured location on the Roadmap.	The measured points will appear as 'white dots' along the Roadmap. The user is able to view and click all measured points along the Roadmap.	Provides the user with a visual aid of where the values were measured during pullback.
Allow multiple length measurements in the Physiology Co-Registration results tab	The user can perform only one length measurement at a time along the vessel or the trend line.	The user can perform multiple length measurements at a time along the vessel or the trend line.	New feature enhancement.
Enhancement related to Tri-registration workflow	After performing Tri-registration between Angiography, Physiology, and IVUS the user must switch between screens to see the desired view.	After performing Tri-registration a joint display comprising of Angiography, Physiology, and IVUS Co-Registration data is provided on one screen.	Improvement to workflow
Enhancement related to Tri-registration workflow	The user needs to perform an IVUS Co-Registration first and then perform Physiology Co-Registration using the same Roadmap image in order to obtain Tri-Registration.	The workflow is flexible as the user can perform Co-Registrations in any order.	Improvement to workflow
Addition of "iFR Estimated" calculation on the GUI	When performing a single length measurement the system calculates and displays the number of yellow pressure drops within a length measurement, this is called "iFR drop in selection" (which is not a new feature). The physician then manually adds this number to the iFR distal value shown on the screen as a supplement reference.	When performing single or multiple length measurements the system calculates the number of the yellow pressure drops within the length measurement, this is called "iFR drop in selection". The System adds this number to the iFR distal value and displays the result on the screen as "iFR Estimated."	The result of the calculation is shown on the screen as an iFR Estimated value. This value will now be displayed for ease of use to the clinician.

Proposed Modification	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comments
Compatibility with new Volcano FFR Software (SW) version 2.5	Compatible with FFR Software version 2.4.1	Compatible with FFR Software version 2.5	Compatible with the latest software version
Compatibility with the new pressure wire Verrata® Plus	Compatible with Verrata pressure wire	Compatible with Verrata Plus pressure wire	Additional pressure wire compatibility added
Removal of the use of the ECG signal	The system can process Co-registration with or without an ECG signal: -if ECG is used the System uses the ECG signal for automatic angiogram frame selection -if ECG is not used System selects the middle frame of the angiogram.	Removed the ECG signal option. The System automatically selects the angiogram frame.	Removed ECG option from workflow. The option to modify the frame selection or manually select an angiogram frame is still available to the user.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
The subject device provides additional angiographic features to the predicate device SyncVision System, cleared under K161756. There are no hardware or component changes. The software changes are enhancements to the current features, administrative, infrastructure, and service changes.

This submission is for software and subsequent labeling changes. The devices are identical in terms of:

- Indications for use,
- Design,
- Materials,
- Specifications,
- Principles of Operation, and
- Fundamental Scientific Technology.

A comparison of the technological characteristics between the new device and those of the predicate device is provided in the Technological Comparison table below:

Technological Comparison

Technical Attributes	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comment
Indications for Use	The SyncVision System is an image acquisition and processing system. It is indicated for use as follows: • To provide quantitative information regarding the	The SyncVision System is an image acquisition and processing system. It is indicated for use as follows: • To provide quantitative information regarding the	Same

Technical Attributes	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comment
	calculated dimensions of arterial segments. • To enhance visualization of the stent deployment region. • To be used in-procedure in the catheterization lab and off-line for post-procedural analysis. • To obtain a co-registration of an angiographic x-ray image and IVUS images. • To obtain a co-registration of an angiographic x-ray image and intravascular blood pressure values.	calculated dimensions of arterial segments. • To enhance visualization of the stent deployment region. • To be used in-procedure in the catheterization lab and off-line for post-procedural analysis. • To obtain a co-registration of an angiographic x-ray image and IVUS images. • To obtain a co-registration of an angiographic x-ray image and intravascular blood pressure values.	
User Group	Intended for use by clinicians, technicians and research personnel	Intended for use by clinicians, technicians and research personnel	Same
Application	Accessory to existing vessel image systems for image manipulation and co-registration and to provide vessel measurements	Accessory to existing vessel image systems for image manipulation and co-registration and to provide vessel measurements	Same
Use Environment	To be used in the catheterization lab; online during the procedure, and offline for immediate post-procedural analysis.	To be used in the catheterization lab; online during the procedure, and offline for immediate post-procedural analysis	Same
Compatibility with the catheter-laboratory fluoroscopy Systems	- Siemens Axiom Artis & Siemens Artis Zee - Philips Allura Xper FD10/20 & Philips Allura Clarity - GE Innova - Toshiba Infinix - Shimadzu Trinias/Voyager	- Siemens Axiom Artis & Siemens Artis Zee - Philips Allura Xper FD10/20 & Philips Allura Clarity - GE Innova - Toshiba Infinix -Shimadzu Trinias/Voyager - Philips Intuis -Philips Azurion (Allura R9)	Additional systems
Compatible with the following IVUS system & catheters	- Volcano s5/CORE Systems with SW version 3.2.2 and above, and FM software version 2.4.1 - Eagle Eye Platinum IVUS catheter - Verrata pressure guide wire	- Volcano s5/CORE Systems with SW version 3.4 and 3.5, and FM software version 2.5 - Eagle Eye Platinum IVUS catheter - Verrata pressure guide wire -Verrata Plus pressure guide wire	Updated to current s5/CORE Systems software, and the FM software version 2.5. Additional pressure guide wire compatibility.

Technical Attributes	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comment
Compatible ECG Monitors	Compatible with most modern ECG monitors which are equipped with an Auxiliary output signal and are commonly used in the cath-lab and have analog outputs (input range ±10V). ADC resolution: 16 bit. Minimum amplitude required is 200mV. The configuration of the SyncVision System is compatible with common layouts and configurations of catheter laboratories.	N/A	ECG acquisition is no longer required for angiogram frame selection
Image Source	Angiography/fluoroscopy/ Intravascular Ultrasound (IVUS)/ FFR/iFR pressure wires	Angiography/fluoroscopy/ Intravascular Ultrasound (IVUS)/ FFR/iFR pressure wires	Same
Source Image Type	Native angiography/fluoroscopy/ultrasound images	Native angiography/fluoroscopy/ultrasound images	Same
Image Size	Any image size, according to native source image	Any image size, according to native source image	Same
Image Depth support	X-Ray: 8 bit grayscale IVUS: 24 bit RGB or converted to an 8 bit grayscale to display IVUS in black & white	X-Ray: 8 bit grayscale IVUS: 24 bit RGB or converted to an 8 bit grayscale to display IVUS in black & white	Same
Image Frame Selection for Measurements	Angiogram - The system automatically presents an image frame, and in most cases this will be a frame in which the vessel is filled with contrast media IVUS – User selectable FFR/iFR – user selectable	Angiogram - The system automatically presents an image frame, and in most cases this will be a frame in which the vessel is filled with contrast media IVUS – User selectable FFR/iFR – user selectable	Same
Manual Override	Manual override of selected angiogram or IVUS image	Manual override of selected angiogram or IVUS image	Same
Quantitative Information	Quantitative Coronary Analysis (QCA) applied to angiogram and IVUS images	Quantitative Coronary Analysis (QCA) applied to angiogram and IVUS images	Same
QCA Interface	The user marks the designated lesion, location, or diameter using a point-and-click input device	The user marks the designated lesion, location, or diameter using a point-and-click input device	Same
QCA Calibration	Optional, using the Guiding Catheter. If a calibration was not performed, only the % stenosis will be calculated and displayed	Optional, using the Guiding Catheter. If a calibration was not performed, only the % stenosis will be calculated and displayed	Same
Edge Detection	Digital edge detection by calculation of the derivatives (or gradients) of the density curve across the lumen and finding their	Digital edge detection by calculation of the derivatives (or gradients) of the density curve across the lumen and finding their	Same

Technical Attributes	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comment
	peak values, followed by least-cost optimization	peak values, followed by least-cost optimization	
QCA Display	Angiogram: Vessel walls superimposed on the vessel image in addition to Minimum Lumen Diameter (MLD) marker line and two reference-point marker lines. IVUS: Diameter is displayed on the IVUS axial image and length is displayed on the IVUS longitudinal view	Angiogram: Vessel walls superimposed on the vessel image in addition to Minimum Lumen Diameter (MLD) marker line and two reference-point marker lines. IVUS: Diameter is displayed on the IVUS axial image and length is displayed on the IVUS longitudinal view	Same
Vessel Measurements	MLD (mm), segment diameter(s) (mm), segment length (mm), reference diameter (mm) and % stenosis	MLD (mm), segment diameter(s) (mm), segment length (mm), reference diameter (mm) and % stenosis	Same
QCA Measurement Precision	-MLD Precision: 0.15 mm - % Narrowing Precision: 5% - Segment Precision: 0.5 mm	-MLD Precision: 0.15 mm - % Narrowing Precision: 5% - Segment Precision: 0.5 mm	Same
IVUS C-Registration Measurements: (Diameter and Length	Diameter: Precision ≤ 0.1mm Length: Precision ≤ 0.5mm	Diameter: Precision ≤ 0.1mm Precision ≤ 0.5mm	Same
Manual Diameter Measurements on axial IVUS images	Precision ≤ 0.1mm	Precision ≤ 0.1mm	Same
Area Measurement Precision	Precision ≤ ±0.1mm^2	Precision ≤ ±0.1mm^2	Same
FFR/iFR Co-Registration Length Measurements	Precision ≤ 2.0 mm	Precision ≤ 2.0 mm	Same
Balloon/Stent Enhancement	Enhanced visualization of the stent deployment region by tracking and alignment of balloon markers, and averaging of multiple consecutive frames. Enhancement is performed by means of temporal and spatial filtering of the aligned frames.	Enhanced visualization of the stent deployment region by tracking and alignment of balloon markers, and averaging of multiple consecutive frames. Enhancement is performed by means of temporal and spatial filtering of the aligned frames.	Same
Method	Marker detection and alignment	Marker detection and alignment	Same
Enhancement Algorithm	Enhancement is performed by means of temporal and spatial filtering of the aligned frames	Enhancement is performed by means of temporal and spatial filtering of the aligned frames	Same

Technical Attributes	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comment
Power Supply	Medical grade isolation transformer 600VA - Toroid ISB-060W or compatible	Medical grade isolation transformer 600VA - Toroid ISB-060W or compatible	Same
Joystick	Standard USB, 2-button	Standard USB, 2-button	Same
Joystick Catheterization Table Rail Compatibility	EUR RAIL 10 x 25 mm US RAIL 3/8" x 1 1/8"(9.52x28.57mm)	EUR RAIL 10 x 25 mm US RAIL 3/8" x 1 1/8"(9.52x28.57mm)	Same
Monitor	Flat panel 19" or above monitor with VGA and DVI inputs Resolution 1280x1024 or above	Flat panel 19" or above monitor with VGA and DVI inputs Resolution 1280x1024 or above	Same
Mouse and Keyboard	Keyboard: standard USB keyboard Mouse: Standard USB mouse	Keyboard: standard USB keyboard Mouse: Standard USB mouse	Same
Operating System	Windows 7 64bit Professional Ed.	Windows 7 64bit Professional Ed	Same
Electrical Specifications	Class I equipment, per IEC/EN 60601-1 H/W v2.0: Input 120V to 240V auto voltage selector 50/60Hz Output 120V-240V voltage selector 50/60Hz H/W v2.1: Input 100V to 240V auto voltage selector 50/60Hz Output 100V-240V voltage selector 50/60Hz Minimum power 400VA (at 240V) Minimum outputs 4 (IEC320 C14 socket) Over load protection fuse 100V & 240V On/Off switch Power cord: medical grade minimum wire diameter AWG18 (0.75mm²) 3.5m max length Fuses: 100VA 8.0A, 120VAC: 6.3A, 240VAC: 3.15A	Class I equipment, per IEC/EN 60601-1 H/W v2.1: Input 100V to 240V auto voltage selector 50/60Hz Output 100V-240V voltage selector 50/60Hz Minimum power 400VA (at 240V) Minimum outputs 4 (IEC320 C14 socket) Over load protection fuse 100V & 240V On/Off switch Power cord: medical grade minimum wire diameter AWG18 (0.75mm²) 3.5m max length Fuses: 100VA 8.0A, 120VAC: 6.3A, 240VAC: 3.15A	H/W v2.0 not compatible with SyncVision SW version 4.1
Environmental Conditions	Ambient temperature range: +15°C to +35°C (+59°F to +95°F) Relative humidity range: 30% - 85% Atmospheric pressure range 700hpa to 1060hpa	Ambient temperature range: +15°C to +35°C (+59°F to +95°F) Relative humidity range: 30% - 85% Atmospheric pressure range 700hpa to 1060hpa	same
Power Consumption	~400W,minimum power 400 VA (@ 240V)	~400W,minimum power 400 VA (@ 240V)	Same
Workstation Dimensions	Case Type: Super Midi-Tower	Case Type: Super Midi-Tower	No change in hardware: Correction of

Technical Attributes	Predicate Device SyncVision System SW 4.0/HW 2.1 K161756	Proposed Device SyncVision System SW4.1/HW2.1	Comment
	H/W v2.0 Measurements: (without front panel) 210mm (W) x 460mm (H) x 460mm (D) H/W v2.1 Measurements: 162 mm (W) x 396 mm (H) x 510 mm (D)	Measurements: (without front panel) 176 mm (W) x 430 mm (H) x 550 mm (D)	the dimensions only

SUMMARY OF NON-CLINICAL PERFORMANCE DATA:
Non-clinical performance testing has been performed on the SyncVision System software and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance documents:

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.0, 2006). FDA/CDRH recognition number 13-32.

Applicable testing was performed as required by the Quality System to evaluate the modifications to the SyncVision System software. The following tests were conducted:

- Software Verification
  - Unit, Integration, and System Level/General Verification Software Testing
  - QCA Verification
  - IVUS co-Registration Verification
  - FM Co-Registration Verification
- Software Validation
  - FM Co-Registration Visual Validation
- Usability Validation
  - Simulated Use, Design & Usability/Human Factors Engineering Validation Test

The test results demonstrated passing results in all cases when compared to acceptance criteria defined in the respective test plans and protocols.

Sterilization testing was not required as there are no sterile components or accessories for the modified SyncVision System which consists of hardware and software.

Biocompatibility is not applicable to this submission as there are no materials in the modified SyncVision System that come into direct or indirect contact with the patient. Contact with the user involves computer hardware accessories only, i.e., keyboard, mouse.

Electromagnetic compatibility and electrical safety testing was not required for the software changes that are the subject of this Premarket Notification. There were no design changes to the hardware, cables or power supply as a result of the proposed software changes. Therefore it was determined that packaging validation, electrical safety, electromagnetic compatibility, and acoustic noise level testing were not required.

SUMMARY OF CLINICAL PERFORMANCE DATA:

The SyncVision System did not require clinical data since substantial equivalence to the currently marketed predicate device was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

These attributes demonstrated that the clinical performance of the modified device is substantially equivalent to the predicate device.

CONCLUSION:
Completion of these tests and the differences between the new SyncVision System and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) submission, the SyncVision System is considered substantially equivalent to the currently marketed predicate device.