DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 5, 2016

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

Re: K161756
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: June 27, 2016
Received: June 28, 2016

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 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 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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161756

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 pressures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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PHILIPS

510(k) Summary Revised

SPONSOR: Philips Volcano
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DATE OF SUBMISSION: June 24, 2016

DEVICE: Image-intensified fluoroscopic x-ray system

TRADE NAME: SyncVision System

COMMON NAME: SyncVision System

PRODUCT CODE: OWB

CLASSIFICATION: 21 CFR 892.1650
Class II Device

PANEL: Radiology

PREDICATE DEVICE: Volcano SyncVision System, K151904

DEVICE DECRISPTION:
The current standard procedure in the catheterization laboratory for utilizing x-ray, IVUS image streams, and FFR/iFR pressure measurements calls for referencing the native x-ray, IVUS imaging streams, and FFR/iFR intravascular blood pressure values 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 and IVUS image streams/FFR/iFR intravascular blood pressure values visually on adjacent windows on the same display. The SyncVision System is displayed on a monitor that is situated next to the native x-ray and IVUS image streams/FFR/iFR intravascular blood pressure values in either the catheterization lab or in the control room. The System provides a means to view the angiographic and IVUS image streams or FFR/iFR intravascular blood pressure values on a single display and automates the manual registration processes performed by the physician.

The System is comprised of a workstation, LCD monitor, keyboard, mouse and an isolation transformer installed in the control room of the catheterization lab, as well as a user input device (joystick) installed in the procedure room. The workstation is comprised of a PC equipped with an internal high-resolution dual channel frame grabber, a high-performance graphic processing card and a data acquisition card for ECG signal acquisition. The joystick allows the user to control all of the functions of the System from the procedure room. Cables connect the workstation to data sources which are an input device; the joystick previously mentioned, the x-ray imaging system, the IVUS imaging/FFR/iFR intravascular pressure measurement system, and the ECG monitor. 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 is an image acquisition and processing workstation situated in the coronary catheterization lab and intended to be used during coronary catheterizations. The SyncVision System captures angiographic and intravascular ultrasound (IVUS) image streams and FFR/iFR displayed value streams and performs the following display functions for assisting the interventional cardiologist:

- During Lesion Evaluation; angiogram and IVUS image selection, quantitative coronary measurements (lesion diameters, length, % stenosis), vessel region enhancement and vessel region stabilization are performed instantly and online.
- During Device Positioning, Deployment and Post-deployment; an on-line image stream derived from the native angiographic image stream that is enhanced and stabilized, is displayed side-by-side to the native angiographic and IVUS image streams.
- Import and display of image data from endoluminal modalities, leading to a joint display of images acquired by x-Ray and endoluminal imaging and corresponding to same selected luminal locations or segments (also known as co-registration of such modalities).

The Co-Registration is an automation of a manual workflow process used by interventional cardiologists today. The manual procedure in the catheterization lab for utilizing x-Ray, IVUS

image streams and FFR/iFR displayed value streams calls for referencing the native x-ray and IVUS image streams/FFR/iFR displayed value streams of the patient's vasculature separately on different displays. This common configuration requires the cardiologist to estimate an identical location on the patient's vasculature on the two native image streams (x-ray and IVUS/FFR/iFR) 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 or FFR/iFR displayed value streams automatically on adjacent windows on the same display.

INTENDED 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.

COMPARISON OF CHARACTERISTICS:
This submission is for software and labeling changes, and expansion of the Indications for Use. The devices are identical in terms of design, materials, specifications, principles of operation, and fundamental scientific technology. There are no hardware or component changes. The software changes add new features, administrative, and infrastructure changes. A summary of the major changes and compatibility is provided in **Table 1**, Comparison Matrix of Changes, below with the changes in bold text.

Table 1: Comparison Matrix of Changes

Technical Attributes	Proposed SyncVision System SW 4.0/HW 2.1	Predicate Device SyncVision System SW3.2/HW2.1 K132558	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 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**	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.	Expansion of the Indications for Use to include the FFR/iFR Co-Registration functionality

Technical Attributes	Proposed SyncVision System SW 4.0/HW 2.1	Predicate Device SyncVision System SW3.2/HW2.1 K132558	Comment
	intravascular blood pressure values		
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	Increased through x-ray qualification process
Compatible with the following IVUS system & catheters	- Volcano s5/CORE System 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 (mobile or integrated configurations) with SW version 3.2.2 and above - Eagle Eye Platinum IVUS catheter	Added compatibility due to the new FFR/iFR features
Image Source	Angiography/fluoroscopy/ Intravascular Ultrasound (IVUS)/ **FFR/iFR pressure wires**	Angiography/fluoroscopy/ Intravascular Ultrasound (IVUS)	Added new FFR/iFR pressure wire as a source
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	Added FFR/iFR Co-Registration functionality

PERFORMANCE DATA:
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 and Validation
- Simulated Use Validation

The test results were found to be acceptable by 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.

CONCLUSION:
Completion of these tests concluded that the proposed SyncVision System is substantially equivalent to the predicate device.