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
Sr. Regulatory Affairs Specialist
1 Fortune Drive
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July 31, 2015

Re: K151904
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: July 10, 2015
Received: July 13, 2015

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,

Robert Ochs, Ph.D.
Acting 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)*

K151904

Device Name

SyncVision System

Indications for Use *(Describe)*

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.

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**

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**SUBMISSION DATE**: July 10, 2015

**TRADE NAME**: SyncVision System

**COMMON NAME:** SyncVision System

**PRODUCT CODE**: OWB

**CLASSIFICATION**: 21 CFR 892.1650, Class II Device

**REGULATION NAME**: Image-Intensified Fluoroscopic X-Ray System

**PANEL**: Radiology

**PREDICATE DEVICE**: Volcano SyncRX System, K132558

**PRODUCT CODE**: OWB

**CLASSIFICATION**: 21 CFR 892.1650, Class II Device

**REGULATION NAME**: Image-Intensified Fluoroscopic X-Ray System

**PANEL**: Radiology

**DEVICE DECRISPTION**:
The current standard procedure in the catheterization laboratory for utilizing x-ray and IVUS image streams calls for referencing the native x-ray and IVUS imaging 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 and IVUS image streams 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 in either the catheterization lab or in the control room. The System provides a means to view both the angiographic and IVUS image streams on a single display and automates the manual registration processes performed by the physician.

The System are comprised of a workstation, and 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 mentions, the x-ray imaging system, IVUS imaging 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 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.
- Display of native image / data streams used before or during trans-catheter cardiovascular interventions, leading to a joint display of images corresponding to the same selected vascular locations or segments (also known as co-registration).

The Co-Registration is an automation of a currently manual workflow process used by interventional cardiologists today. The current standard procedure in the catheterization 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 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) on two separate displays. The SyncVision System simply 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.

**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.

**COMPARISON OF CHARACTERISTICS**:
This submission is for software and labeling changes only. 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, expand on current features, and administrative and infrastructure changes as described below.

New Features

- Bookmarks – Add/Remove automatic and user-defined bookmarks on Co-Registration sequences
- On-screen Keyboard
- Added Rapid Review feature, an instant replay option of a predefined number of proximal and distal frames to the region of interest played in a loop
- Procedure Management search option improved to allow user to search by procedure ID
- Auto system shutdown added

Expanded user features

- Additional measurement editing of IVUS Measurements, perform area and diameter measurements and edit existing measurements
- Roadmap pathway editing improvements for more intuitive use
- Roadmap image zoom factor widened for a larger image of the pullback region
- Improve Co-Registration error messages – Improve usability of online co-registration error messages (minor GUI change)
- Offline Mode allows user to perform QCA and VE on a stored procedure offline
- Expanded recorded Co-Registration results when exporting to an AVI file

Administrative changes

- The application user interface and Operator's Manual is currently in English only and will be expanded to the following languages:, Danish, Finnish, French, German, Hungarian, Italian, Dutch, Polish, Portuguese, Spanish, Swedish, and Norwegian, Czech, Turkish and Russian
- New warning message to alert user when x-ray frame rate used during IVUS pullback is outside the recommended frame per second rate (fps)
- QCA/VE Tab Name change to Reports Tab
- QCA feature will be a selectable option versus a standard option during system setup

Infrastructure Modifications

- Various infrastructure changes
    - Export controller – The new version will have new Export controller that performs all exporting of data in one place: Export session(s), Export sequence, export AVI movies, export snapshots
    - Create data converter – application has the ability to convert old data to the new format for backward compatibility
    - Keep procedure metadata – basic procedure information regarding procedures that have been deleted are saved by the automatic archiving process
    - Save procedure statistics – statistic data regarding every session is saved, this data is used for complaint investigation
    - Procedure data versioning – Procedure data will include version number in order to associate it with the version of application used
    - Modifications for Co-Registration dump
    - Improve tracking at x-ray image boundaries, collimator detection improvements and x-ray image mask
    - Application setup modifications: installation CD improvements for SyncVision and the Stand Alone Viewer

**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.