February 11, 2019

Volcano Corporation
Kimberly Simon
Regulatory Affairs Specialist
3721 Valley Centre Drive, Suite 500
San Diego, California 92130

Re: K190078
Trade/Device Name: IntraSight System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, DSA, DSK
Dated: January 15, 2019
Received: January 16, 2019

Dear Kimberly Simon:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K190078

Device Name

IntraSight System

Indications for Use *(Describe)*

The IntraSight System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature. As an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures. The pullback feature of the Spinvision (PIMr) withdraws the imaging core within the protective sheath for a maximum of 15 cm.

The FFR Modality is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

The iFR Modality is intended to be used in conjunction with currently marketed Volcano pressure wires. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89 which represents an ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used as for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.

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.

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510(k) SUMMARY

SPONSOR:	Volcano Corporation 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130
CONTACT/SUBMITTER:	Kimberly Simon Regulatory Affairs Specialist Philips Volcano 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130 Tel: (858) 720-4113
DATE PREPARED:	January 15, 2019
DEVICE:	IntraSight
TRADE NAME:	IntraSight
COMMON NAME:	System, Imaging, Pulsed Echo, Ultrasonic
CLASSIFICATION:	21 CFR Part 892.1560 IYO: Ultrasonic Pulsed Echo Imaging System 21 CFR Part 870.2900 DSA: Patient Transducer and Electrical Cable 21 CFR Part 870.1110 DSK: 870.1110 Blood Pressure Computer
PREDICATE DEVICE:	Volcano s5i/CORE and CORE Mobile Precision Guided Therapy Systems (K173860)
DEVICE DESCRIPTION:	The IntraSight System provides qualitative and quantitative evaluation of vascular morphology in the coronary arteries and peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures. The IntraSight System interfaces with Volcano Intravascular Ultrasound (IVUS) Imaging Catheters and pressure wires. When operating in the IVUS mode, the IVUS catheter uses a transducer near the distal tip to emit and receive high frequency sound waves. The system is then able to analyze the signal that is received by the transducer to differentiate between vessel structures and produce a 360° cross-sectional, tomographic image. When operating in the pressure mode, the system acquires intraluminal data from

a pressure guide wire while simultaneously taking aortic pressure data from the established catheterization lab equipment. Catheters and guide wires are connected to the system via the Patient Interface Module (PIM).

INTENDED USE:

The IntraSight system is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature. As an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures. The pullback feature of the Spinvision (PIMr) withdraws the imaging core within the protective sheath for a maximum of 15 cm.

The FFR Modality is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

The iFR Modality is intended to be used in conjunction with currently marketed Volcano pressure wires. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89 which represents an ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used as for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.

COMPARISON OF CHARACTERISTICS:

The IntraSight System is a modification to the currently marketed CORE Integrated System. The IntraSight System is a modification to the currently marketed CORE System cleared of K173860. The modifications to the CORE System include:

- Reduced functional capability – removal of the VH IVUS modality
- New image signal processing hardware and software, as the current image signal processing hardware is going end-of-life
- Updated software platform (Endeavour App Engine) to provide an improved User Interface
- Updated secondary user interface (bedside controller) to provide an improved ease of use
- Update to the FM-PIM in order to provide an adaptor for compatibility to the Verrata pressure wires, changes to PIM firmware, and fluid ingress protection

None of these modifications effect or alter the fundamental scientific technologies of the currently marketed device.

PERFORMANCE DATA:

Performance testing completed for a determination of substantial equivalence included the following:

- Master Safety Testing (EMC and Electrical Safety)
- Environmental Testing
- Design Verification
- Software Verification and Validation
- Packaging Validation
- Simulated Use / Usability Validation
- Image Validation