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
Elaine Alan
Senior Regulatory Affairs Specialist
1 Fortune Drive
Billerica, Massachusetts 01821

Re: K143701
Trade/Device Name: Eagle Eye Platinum (EEP) Digital IVUS Catheter Line
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: June 23, 2015
Received: July 16, 2015

Dear Elaine 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.

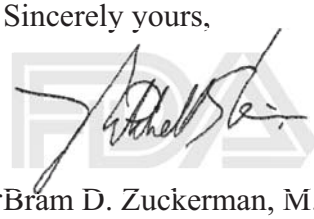
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143701

Device Name

Eagle Eye Platinum (EEP) Digital IVUS Catheter Line

Indications for Use *(Describe)*

The Eagle Eye® Platinum (EEP) Digital IVUS Catheter Line, including the Eagle Eye Platinum catheter, Eagle Eye Platinum ST catheter and the PV.014P catheter, are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. These devices are not currently indicated for use in the cerebral vessels.

The Eagle Eye® Platinum (EEP) Digital IVUS Catheter Line is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures

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

SPONSOR:

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CONTACT/SUBMITTER:

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Tel: (858) 764-1281

DATE OF SUBMISSION: December 21, 2014

DEVICE: Eagle Eye Platinum (EEP) Digital IVUS Catheter Line

Trade Name: Eagle Eye Platinum (EEP) Digital IVUS Catheter Line

Common Name: Diagnostic Intravascular Catheter

Classification and Product Codes:

CFR Number	Class	Product Code
21 CFR 870.1200 Diagnostic Intravascular Catheter	II	OBJ
21 CFR 892.1570 Diagnostic Ultrasound Transducer	II	ITX

PREDICATE DEVICE:

Eagle Eye Platinum (EEP) Digital IVUS Catheter (K092596)
Eagle Eye Platinum Short Tip (EEP-ST) Catheter (K120697)

DEVICE DESCRIPTION:

The EEP line of digital IVUS catheters consists of the following products:

- Eagle Eye Platinum Catheter, Part # 809746001, Model 85900P
- Eagle Eye Platinum Short Tip Catheter, Part # 400-0200.141, Model 85900PST
- Visions PV .014 Platinum, Part # 400-0200.233, Model 85910P

The EEP line of catheters incorporates a cylindrical ultrasound transducer array located near the distal tip of the catheter. The array radiates acoustic energy into the surrounding tissue and detects the subsequent ultrasonic echoes. The information from the echoes is used to generate real-time images of the coronary or peripheral vessels.

All of the EEP line of catheters utilizes an internal lumen that allows the catheters to track over a 0.014" (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The EEP line catheters are introduced either percutaneously or via surgical cut down into the vascular system.

The EEP line of catheters may be used with the In-Vision Imaging System, Volcano s5™, Volcano s5i™, Volcano CORE Mobile, and Volcano CORE imaging systems. The catheters are designed to work with Volcano VH IVUS system software v1.2 or higher. This catheter will not operate if connected to any other imaging system.

INDICATIONS FOR USE:

The **Eagle Eye® Platinum (EEP) Digital IVUS Catheter Line,** including the Eagle Eye Platinum catheter, Eagle Eye Platinum ST catheter and the PV.014P catheter, are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. These devices are not currently indicated for use in the cerebral vessels.

The **Eagle Eye® Platinum (EEP) Digital IVUS Catheter Line is** designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

COMPARISON OF TECHNOLOGICAL CHARACTERISICS:

The modification made to the EEP line of catheters (change in hydrophilic coating) does not affect the intended use of the device or technologies included as part of the device product line and it does not alter the fundamental scientific technologies. The indications for use are identical to those of the currently marketed devices (EEP; K092596 and EEP-ST K120697). The modified catheters are substantially equivalently to currently marketed predicate devices.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the modified device. Bench testing was conducted against known standards or product specification and evaluated the following:

- Friction Force
- Coating Adhesion
- Particulate Generation

All bench testing was successfully completed.
Biocompatibility testing was conducted on the device and the following tests were successfully completed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity
- Pyrogenicity
- ASTM Hemolysis
- Partial Thromboplastin Time
- *In vivo* Thromboresistance
- C3a Complement Activation
- SC5-b Complement Activation
- Bacterial Endotoxins (LAL)
- LEAP Latex Elisa for Antigenic Protein
- Platelet and Leukocyte Counts
- Genotoxicity

The successful completion of performance testing and biocompatibility testing concluded that the modified Eagle Eye Platinum catheters are substantially equivalent to the currently marketed Eagle Eye Platinum catheters.