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

October 26, 2016

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

Re: K160583
Trade/Device Name: REFINITY Rotational Intravascular Ultrasound (IVUS) Catheter
REFINITY Short Tip Rotational Intravascular Ultrasound (IVUS) Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, DQO
Dated: September 21, 2016
Received: September 22, 2016

Dear Brian Park:

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.

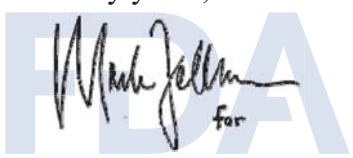
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



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)*
K160583

Device Name
REFINITY Rotational Intravascular Ultrasound (IVUS) Catheter
REFINITY Short Tip Rotational Intravascular Ultrasound (IVUS) Catheter

Indications for Use *(Describe)*

The REFINITY (or REFINITY ST) Rotational IVUS Catheter (REFINITY or REFINITY ST catheter) is intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. REFINITY (or REFINITY ST) catheters are 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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PRECISION GUIDED THERAPY

- **510(k) SUMMARY**

The 510(k) Summary is submitted as required by section 807.92(a)

SPONSOR:	Volcano Corporation 2870 Kilgore Road Rancho Cordova, CA 95670
CONTACT/SUBMITTER:	Brian Park Regulatory Affairs Specialist Volcano Corporation 3721 Valley Centre Dr. Suite 500 San Diego, CA 92130 Tel: (858) 720-4176 Fax: (858) 481-1027
DATE OF SUBMISSION:	March 28, 2016
DEVICE:	Refinity Rotational Intravascular Ultrasound (IVUS) Catheter Refinity Short Tip Rotational Intravascular Ultrasound (IVUS) Catheter
Trade Name:	Refinity Rotational IVUS Catheter Refinity Short Tip Rotational IVUS Catheter
Common Name:	IVUS Imaging Catheter
Classification:	Class II Device 21 CFR Part 870.1200 Intravascular Ultrasound Catheter (OBJ) 21 CFR Part 870.1200 Intravascular Ultrasound Catheter (DQO)
PREDICATE DEVICE:	Volcano Revolution® 45MHz Rotational Intravascular IVUS Imaging Catheter Model Number: 89000 Product Code: OBJ K080891, Cleared on May 12, 2008 Secondary Predicate Volcano Eagle Eye® Platinum Short Tip Catheter Model Number: 85900PST Product Code: OBJ, ITX K120697, Cleared on April 5, 2012

DEVICE DESCRIPTION:	The Refinity and Refinity Short Tip (ST) Rotational IVUS Imaging Catheter consists of two main assemblies: the imaging core and the catheter body. The catheter body is comprised of four sections: a distal section with a .014" compatible rapid exchange guide wire lumen and clear imaging window, a mid-shaft section, a braided proximal shaft, and a telescoping section. The distal, mid, and proximal sections comprise the usable length or working length of the catheter. The telescoping section remains outside of the guiding catheter. The telescoping section allows the imaging core to be advanced and retracted for up to 15 cm of linear movement. The corresponding movement of the transducer occurs from the proximal end of the guidewire exit port to the proximal end of the window portion of the distal section. The imaging core is composed of a hi-torque, flexible, rotating drive cable with a distal outward looking ultrasonic transducer. An electromechanical connector interface at the proximal end makes the connection to the patient interface module (PIM). The PIM-catheter interface consists of an integrated mechanical drive assembly and electrical connection. A flushing port with a one-way valve is used to displace the air initially present within the catheter. The catheter must be flushed with sterile heparinized normal saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way valve helps retain saline in the catheter during use. The catheter body has a distal guide wire lumen with a proximal exit port located 15.5mm (for the short tip model) or 22mm (for the standard tip model) from the distal end. One radiopaque (RO) marker band is embedded 0.5 cm from the tip. In addition, insertion depth indicators are located on the catheter body at 90 cm and 100 cm. The catheter is packaged with a sterile PIM cover, 3 cc and 10 cc syringes, and 13 in extension tubing with a 3-way stopcock. The catheter is for use with the Volcano s5® and CORE® imaging systems with software V3.x.x.
INDICATIONS FOR USE:	The REFINITY (or REFINITY ST) Rotational IVUS Catheter (REFINITY or REFINITY ST) is intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. REFINITY (or REFINITY ST) catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

	The statement, "REFINITY (or REFINITY ST) catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures." is being added to the Indications for Use in order to clarify that the device is not intended to be used as a standalone device but needs to be placed in the vasculature under standard angiographic guidance. This is a clarification to the Indications for Use and not an expansion of its use or a substantive change.
COMPARISON OF CHARACTERISTICS:	The modified device is substantially equivalent to the currently marketed Revolution device. Both devices are rotational IVUS imaging catheters. In fact, the proposed Refinity has the identical ultrasound transducer and rotational drive mechanism as the predicate Revolution and differs in the outer polymer shaft design, hydrophilic coating and sterile pouch design. The working lengths are identical for both the predicate and modified devices but the shaft of the modified device is smaller in diameter than the predicate. The indications for use are identical for both devices. The outer materials of the Refinity differ from the Revolution. In general, the distal patient contacting portion of the Revolution catheter is made of tubing made of single and blended low, medium and high density polyethylenes. The distal patient contacting portion of the Refinity is made of tubing made of single and blended polyethylene, polyether block amide and polyimide materials. The Refinity tubing materials allow for smaller outer diameters. In the proximal portion of the catheter the Revolution has a proximal shaft made of polyetherimide and secondary telescope made of polyimide which the Refinity replaces with a shaft made of braided stainless steel in polyimide sandwiched between an inner layer of blended polytetrafluoroethylene (PTFE) and polyimide and an outer layer of polyether block amide. The Revolution is coated with a silicone based lubricious coating while the Refinity is coated with a hydrophilic coating. Finally, the Revolution is packaged in a pouch that is made of mylar film and Tyvek® while the Refinity is packaged in a pouch that is made of a stronger nylon/low density polyethylene/high density polyethylene film and Tyvek®.
PERFORMANCE DATA:	Non-clinical device testing was conducted to confirm the performance of the device. Bench testing was conducted against known standards or the product specification and evaluated the following:

K160583

	• Visual Inspection: Sample catheters were visually inspected for defects such as cracks, kinks or other damage visible to the unaided eye and for extraneous surface matter using 10X magnification. Acceptance criteria: No visual defects. • Dimensional Verification: Tubing lengths and outer diameters were measured. Acceptance criteria: All dimensions must meet product specifications. • Catheter Prep: Sample catheters were prepped for use by flushing the lumen with sterile saline. Acceptance criteria: Samples need to meet product specifications for flushing and leaks. • Tensile Strength: All bond joints were pull tested to assess their tensile strengths. Acceptance criteria: Bond joint tensile strengths must meet product specifications. • Monorail Tear Strength: The Refinity includes a monorail rapid exchange guide wire lumen that allows the catheter to be passed over a guide wire for delivery and placement within a vessel. The amount of force needed to tear through the entire length of the guide wire lumen was measured on sample catheters. Acceptance criteria: The tear strength of the guide wire lumen must meet product specifications. • Guide Wire Movement: The monorail guide wire lumen is designed to accommodate a 0.014" guide wire. The compatibility of the Refnity's guide wire lumen was tested on sample catheters. Acceptance criteria: Sample catheters must meet product specifications in regards to movement over a 0.014" guide wire. • Torsion: In clinical use, users may torque or twist the shaft of the Refinity catheter. The torsional strength of the Refinity was tested. Acceptance criteria: Sample catheters must meet product specifications in regards to minimum turns to failure. • The Refinity has a telescoping section that allows the user to pull back the imaging core up to 15 cm in length in order to image the inside of a vessel. The amount of force needed to operate the telescope after initial opening was measured. Acceptance criteria: Sample catheters must meet the product specification for the maximum force needed to operate the telescope after its initial opening. • Force to Overextend the Telescope: The force to completely pull out the telescope section of the Refinity catheter was measured. Acceptance criteria: The amount of force required to completely pull the telescope section out of the catheter must meet product specifications. • Particulate: Since the distal portion of the Refinity catheter is coated with a hydrophilic coating, particulate testing is performed to verify the integrity of the coating. The catheter is

	prepped and placed into a water filled tube connected to a light obscuration liquid particle counter. A reservoir of water is connected to the proximal end of the water filled tube where the catheter is introduced to provide a constant supply of water during the test. The particle counter draws 10 ml of water surrounding the catheter into a measurement chamber and automatically counts the number of particles that are ≥10 µm, ≥25 µm and ≥50 µm in size. The tester does this a total of 5 times so that the particles in a total of 50 ml of water are tested. Acceptance criteria: The number of particles counted must meet product specifications per USP 788. • Adhesion: Since the distal portion of the Refinity catheter is coated with a hydrophilic coating, the integrity of the coating is testing with an adhesion test. The adhesion test uses adhesive tape which is applied to the coated section of the catheter. The adhesive tape is then quickly pulled from the catheter and checked to see if any coating has been removed. Acceptance criteria: Adhesion must meet product specifications. • Friction: Since the distal portion of the Refinity catheter is coated with a hydrophilic coating, the lubricity of the coating is tested with a friction test. A pig aorta is cut open and two pieces are mounted to metal plates with the inside surface of the aorta facing up. The metal plates are mounted on the lower hydraulic jaws of a force tester. Sample catheters are clamped between the aortic tissues on the plates. The top end of the catheter is clamped in the upper clamps of the force tester. The plates and test sample are placed in a water tank. The force tester is activated and pulls the test catheter through the aortic tissue mounted on the metal plates at a speed of 12”/minute. The frictional force experienced by the catheter as it is pulled through the tissue mounted on the plates is automatically recorded by the force tester. Acceptance criteria: The frictional force measured must meet product specifications. • NURD (Non-Uniform Rotational Distortion): The Refinity includes a rotating IVUS transducer that provides images inside a vessel. The NURD test verifies that the drive cable rotates smoothly at a uniform speed while in a simulated tortuous path. During the test, the transducer is placed in a fixture and images are captured that allow the angular separation between diametrically opposed objects to be measured. Acceptance criteria: The angular separation between diametrically opposed objects must meet product specifications. • Rapid Deployment: The baseline capacitance of the Refinity catheter is measured. The catheter is then placed in a test fixture. The fixture pulls back the telescope section in each test

K160583

	sample in a uniform fashion. After the pull back is performed the catheter is removed from the fixture and the capacitance is re-measured. Acceptance criteria: The capacitance difference must meet product specifications. • Tortuous Pullback: The Refinity catheter is flushed and then tracked over a 0.014" wire through a tortuous path fixture. Once in place, the catheter is attached to a Patient Interface Module (PIM) that is attached to a Volcano imaging system. The imaging system displays the catheter serial number and the PIM is set to a pullback speed of 1mm/sec. The PIM is turned on to start imaging from the catheter. A catheter image is verified and then the PIM is activated to start a pullback. The PIM pulls back the imaging core a length of 15cm through the tortuous path with the catheter imaging. After pulling back the imaging core 15 cm, the PIM automatically stops. The imaging core is pushed back to its distal starting position within the tortuous path fixture. Acceptance criteria: The device must continue to image per product specifications. • Image Life - Acceptance criteria: The catheter must still image after completion of the Rapid Deployment and Tortuous Pullback tests. • Drill Through: Since the transducer element of the Refinity catheter rotates, in a worst case situation, if the transducer is rotating and the user pushes the telescope forward and the distal portion of the catheter shaft is kinked, the transducer could drill through the wall of the catheter and potentially damage the inside of the vessel wall. The drill through test involves simulating this worst case situation. The catheter's telescope is pulled back completely and the catheter is flushed. The acoustic window portion of the distal end of the catheter is bent to a 90° angle. The bent distal section is placed in a test fixture that maintains the 90° bend. The catheter is connected to a PIM and is turned on to rotate the transducer. The rotating transducer is manually advanced to the bend and is manually pushed up against the kinked tubing to see if it can be pushed through the shaft like a drill. The catheter is allowed to image for a maximum of 30 minutes or until the catheter stops imaging. Acceptance criteria: Device must meet product specifications in regards to Drill Through. • Guide Catheter Compatibility: Sample catheters are inserted in a 5F Guide Catheter with an inner diameter of 0.056". Acceptance criteria: Refinity catheters must meet product specifications in regards to Guide Catheter compatibility. • Image Assessment: Five independent end user reviewers and one internal reviewer viewed side by side IVUS pullback videos of the same vessel taken with the Revolution and Refinity

	Catheters. The reviewers did not know which pullback was from the Revolution Catheter and which was from the Refinity Catheter. Each reviewer compared a total of fifteen sets of side by side pullback videos. The reviewers compared the pullback images and rated the axial resolution, lateral resolution, NURD, depth of image penetration and overall image aesthetics. Acceptance criteria: Results must meet the acceptance criteria as stated in the test protocol. • Acoustic emissions: Acoustic emission testing was performed on five Refinity catheters in accordance with a 2008 FDA document, "Information for Manufacturers Seeking Market Clearance of Diagnostic Ultrasound Systems and Transducers". Acceptance criteria: As defined per Track 3 of the FDA requirements document. • Thermal dissipation: Thermal dissipation testing was performed in accordance with EN60601-2-37 using a J type thermocouple because the J type is more flexible and suitable for wrapping around the very small diameter of the catheter sheath surrounding the imaging transducer and a tissue mimicking phantom. Acceptance criteria: As defined in the test protocol. • B-Mode Testing: Six parameters that are relevant to B-mode performance were measured. Also, qualitative visual image brightness and integrity were assessed by three signal processing engineers. Acceptance criteria: As defined in the test protocol. • Biocompatibility testing: Biocompatibility of the raw materials in the Refinity catheter were assessed per ISO 10993. Acceptance criteria: Per 10993 and test protocols. Cytotoxicity: Compared to positive and negative controls, test article must be non-cytotoxic. Sensitization: A grade of 0 at 24 and 48 hours. Intracutaneous Reactivity: Primary Irritation Index should be 0-0.4 (negligible). Difference between the mean score of the test article and control is less than 1.0. Acute Systemic Toxicity: No deaths or evidence of systemic toxicity Material Mediated Pyrogen: Temperature rise of <3.4°C USP Limulus Amebocyte Lysate (LAL): Endotoxin < 20EU/device and Spike recovery between 50% - 200% In Vitro Hemolysis (Direct Contact): Hemolytic Index of 0% – 2% In Vitro Hemolysis (Extract): Hemolytic Index of 0% - 2% Plasma: The average recalcification time of the plasma after exposure to the Refinity must be equivalent to the times for the negative and plasma controls and >50% of the negative control

	C3a Complement Activation: The test article is compared to positive and negative controls SC5b-9 Complement Activation: The test article is compared to positive and negative controls Thromboresistance: No, or minimal thrombosis. No, or small amounts of thrombus and vessel remains patent. Platelet and Leukocyte Counts: Normal Human Ranges of Leukocyte count = 3.4-8.7 x 10^3/µL and Platelet count = 116 - 329 x 10^3/µL Latex Elisa for Antigenic Protein (LEAP) Test: Reporting Limit = 0.03µg/ml Completion of these tests concludes that the Refinity Rotational IVUS Catheter is substantially equivalent to the currently marketed Revolution 45MHz Rotational IVUS Imaging Catheter.
Consensus Standards	The Refinity Rotational IVUS Catheter complies with the following consensus standards: The ISO 10993 series of biocompatibility standards including ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity IEC 60601-2-37:2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment ISO 14971:2007 Medical devices - Application of risk management to medical devices
Conclusion	Completion of all performance tests concludes that the Refinity Rotational IVUS Catheter is substantially equivalent to the currently marketed Revolution 45MHz Rotational IVUS Imaging Catheter.