Section 2: 510(k) Summary

SEP 10 2012

Submitter Name:	Volcano Corporation
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Date Prepared:	April 26, 2012
Device Trade Name:	Vision® PV .035 Digital IVUS Catheter
Device Common Name:	Ultrasonic Imaging Catheter
Classification Name:	Diagnostic Intravascular Catheter, 870.1200 - Class II Diagnostic Ultrasound Transducer, 892.1570 - Class II
Classification Code:	IYN: Ultrasonic Imaging Catheter, Intravascular Ultrasonic Imaging System ITX: Transducer, Ultrasonic, Diagnostic, Intravascular Ultrasonic Imaging System
Predicate Devices:	Volcano Visions PV 8.2 PV IVUS Imaging Catheter, 510(k) Number K071660 Classification Code: OBJ, ITX

Device Description :

The **Visions PV .035 Catheter** is an over-the-wire intravascular imaging catheter with a digital ultrasound transducer at the distal end. The transducer utilizes a 64-element cylindrical array that radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the peripheral vessels.

The **Visions PV .035 Catheter** is introduced percutaneously or via surgical cutdown into the vascular system, and is designed to track over 0.035"-0.038" (0.89-0.97mm) guide wires.

The catheter body has markers 1 cm apart along the working length. There are 25 radiopaque (RO) markers on the distal end of the catheter, starting 1 cm from the imaging plane, with the 25th RO marker overlapping the distal-most wide inked marker. Inked markers (non-radiopaque)

continue along the shaft, spaced 1 cm apart, middle-to-middle, with wider marks indicating 5 cm intervals.

A lubricious GlyDx® hydrophilic coating is applied externally to a distal portion of the catheter.

The **Visions® PV .035 Catheter**, catalog number 88901, catheters may only be used with the In-Vision Imaging System, Volcano s5™ or Volcano s5i™ imaging systems, or later systems. This catheter will not operate if connected to any other imaging system.

Intended Use:

The Visions PV .035 catheters are designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels.

The Visions PV .035 ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

Device Design Requirements:

Biocompatibility, shelf life, sterilization, packaging integrity, safety, and design verification testing have been/will be performed to prove that the materials and manufacturing processes selected for the catheter shaft and body of the **Visions® PV .035 Catheter** do not pose a significant safety risk to the patient.

Substantial Equivalence Discussion:

The **Visions® PV .035 Digital IVUS Catheter** is substantially equivalent to the predicate device in intended use and principles of operation. Predicate device information is below:

Predicate Device Name	Model Number (s)	510(k) Number	Clearance Date
Volcano Visions PV 8.2 PV IVUS Imaging Catheter	88900	K07166	8/31/2007

The **Visions® PV .035 Catheter** uses the same fundamental scientific technologies and has the same intended use as that of the predicate device, the Volcano **Visions PV 8.2 PV IVUS Imaging Catheter**. It is an Over-the-Wire catheter design as is the Volcano **Visions PV 8.2 PV IVUS Imaging Catheter** Model 88900.

The **Visions® PV .035 Digital IVUS Catheter** is a redesign of the catheter body elements of the Volcano **Visions PV 8.2 PV IVUS Imaging Catheter**. The significant design changes are:

Predicate Device (PV 8.2)	Subject Device (PV.035)	Comparison
Proximal Shaft (0.092" to 0.108" OD)	Proximal Shaft (0.092" to 0.108" OD)	PV.035 is a 72D Pebax based single lumen design with the same OD. PV 8.2 is a multi-lumen HDPE design that incorporates the inner lumen.
Inner Lumen (0.043" ID)	Inner Lumen (0.043" x 0.048")	PV.035 and PV8.2 have the same ID and HDPE interface. PV.035 utilizes an independent inner lumen with a pebax outer layer, where PV8.2 is a multi-lumen shaft design.
Connector Assembly	Connector Assembly	PV.035 is identical in design except that it adds an extra 20cm to the connector length utilizing excess microcable currently in the design.
Tip	Tip	PV.035 tip is slightly smaller OD and changes materials to a flexible 63D and 55D Pebax. PV 8.2 uses an HDPE blend. The inner lumen is unchanged.
ESL tubing over proximal scanner seal	Adhesive over proximal scanner seal	PV035 uses the same material for the proximal seal as used on the distal seal, PV8.2 uses an expanded and shrunk PE material instead of adhesive.
RO Marker	Inked and RO markers	PV 8.2 uses a PT/IR marker on the tip but has no other marks on the catheter. PV.035 adds 25 RO markers on the distal inner member and then inked markers along the remaining inner lumen up to the y-arm. The proximal shaft is clear so the inked markers can be visualized.

Packaging materials and methods for the **Visions® PV .035 Catheter** will remain unchanged from that of the predicate device at the time of release pending 510(k) approval. Sterility, EO residuals, Bioburden, LAL, and package integrity testing will be completed to ensure that the

changes to the catheter body shape and materials do not have a negative impact on the packaged device. The shelf life of the **Visions® PV 8.2 PV IVUS Imaging Catheter** will be based upon the data available at the time of product release. The shelf life test plan has been written to include time points up to two years.

The Predicate Device Comparison Tables are contained in the Substantial Equivalence Discussion in **Section 9** of this filing. The predicate comparison table and the supporting information provided in this 510(k) are sufficient to demonstrate that the **Visions® PV .035 Digital IVUS Catheter** is as safe and effective as the legally marked predicate device.

Acoustic Output Reporting Table for Track 3

Transducer Model: PV .035 IVUS catheter **Operating Mode:** B-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm^2	$A_{aprt} > 1$ cm^2		
Maximum index value			0.0162	6.18E-5	-	-	-	#
Associated acoustic parameter	$p_{r.3}$	(MPa)	0.0482					
	W_0	(mW)		2.89E-3	-		-	#
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	0.0850				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	9.00	9.00	-	-	-	#
	Dim of A_{aprt}	X (cm)		0.0160	-	-	-	#
		Y (cm)		0.150	-	-	-	#
Other Information	PD	(μsec)	0.333					
	PRF	(Hz)	2.09E+4					
	p_r @ PII_{max}	(MPa)	0.0495					
	d_{eq} @ PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		N/A*	-	-		
		FL_y (cm)		N/A*	-	-		
	$I_{PA.3}$ @ MI_{max}	(W/cm^2)	0.0680					
Operating Control Conditions	Image Rate: 11.673 Hz Transmits/sector: 1792 Angle: 360 degrees Sector offset: 1.27 mm W01 Factor: 0.5							

Note 1: Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.

Note 2: Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

\# No data reported.

* Device is not focused

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 10 2012

Volcano Corporation
c/o Ms. Marilyn Pourazar
Sr. Director, Regulatory Affairs
3661 Valley Centre Drive Suite 200
San Diego, CA 92130

Re: K121273
Trade Name: Visions PV .035 Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Codes: OBJ
Dated: August 28, 2012
Received: August 29, 2012

Dear Ms. Pourazar:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

510(k) Number (if known):

Device Name: Visions® PV .035 Digital IVUS Catheter

Indications for Use:

The Visions PV .035 catheters are designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels.

The Visions PV .035 ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121273