JUN 7 - 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

Device Generic Name: Angiographic Catheter

Device Trade Name: MEDRAD Vanguard Dx™ Angiographic Catheter

510(k) Number: K050371

Name/Address of Applicant: MEDRAD, Inc.
One Medrad Drive
Indianola, PA 15051

II. Indications

The Vanguard Dx™ catheter is intended for use in the delivery of radiopaque contrast media and common flushing agents to the vascular system.

III. Contraindications

The Vanguard Dx™ is **not** intended for multi-patient use. Vanguard Dx™ is single patient use only.

Vanguard Dx™ is **not** for use in the MRI environment.

Vanguard Dx™ is **not** to be used for drug infusion, chemotherapy, or any other use for which the device is not intended.

IV. Warnings and Precautions

A list of warnings and precautions can be found in the device labeling.

V. Device Description

The Vanguard Dx™ is a sterile, single patient use diagnostic catheter for use in cardiology and radiology during angiography. Vanguard Dx™ is the proprietary name for a family of 30 angiographic catheters. The Vanguard Dx™ is similar to other diagnostic catheters on the market in that it delivers radiopaque fluids and common flushing agents to a specific artery in the cardiovascular system for the purpose of differentiating the vessel from the surrounding anatomy during diagnostic imaging procedures. Vanguard Dx™ is available in 4 French and 5 French sizes. It is offered in both flush and selective styles.

The Vanguard Dx™ catheter was designed to enable the effective use of power injection using smaller diameter catheters while reducing the negative effects seen with many

similar catheters such as jetting, whip, and endovascular damage. The differentiating elements of the of Vanguard Dx™ lies in the combination of small holes near the stem/tip interface and a soft tip with an incorporated restrictor that combine to produce clinically beneficial effects. These effects include the creation of a "cloud" of contrast gently exiting through the side holes, which envelops the tip, rather than a single stream of contrast exiting the tip. This reduces the likelihood of vascular injury and has the potential to enhance image quality. Another effect is that a restrictor is incorporated into the tip that limits the flow through the catheter tip thereby encouraging flow through the catheter side holes. The reduction of forward flow through the tip and resulting dispersion of fluid through the side holes produces more balanced hydraulic forces on the catheter during injections so that random oscillations of the tip and rearward motion of the catheter are effectively reduced or eliminated. The result is a more uniform distribution of fluid around the catheter, reduced trauma to the catheterized artery, increased catheter tip stability during a procedure, and potential for enhanced image quality.

Vanguard Dx™ catheters are designed to mate with commercially available fluid delivery products. The finished catheter is compatible with common contrast agents such as Omnipaque 350, Isovue 370, Optiray 350, Ultravist 370, Renografin 76, and Visipaque 320. Vanguard Dx™ is fully biocompatible including compatibility with human blood, saline, and heparinized saline.

VI. Marketing History

The Vanguard Dx™ catheter has not been marketed in the United States or in any other country.

VII. Biocompatibility Testing

The biocompatibility study was undertaken to verify that the 4 French and 5 French Vanguard Dx™ catheters meet the requirements of ISO 109933-1 through 11

Vanguard Dx Biocompatibility Tests

Tests Performed	Pass / Fail
Cytotoxicity: L929-MEM Elution Test	Pass
Irritation or Intracutaneous Reactivity: Intracutaneous Injection Test	Pass
Systemic Toxicity: System Injection Test	Pass
Material Mediated Pyrogens: Rabbit Pyrogen Test	Pass
Sensitization: Kligman Maximimization Test	Pass
Hemocompatability: In-Vitro Hemocompatability Assay	Pass
Hemocompatability: Hemolysis - Rabbit Blood	Pass
Hemocompatiability: Prothrombin Time Assay	Pass
Hemocompatabililty: Lee & White Clotting Test	Pass
In-Vivo Thrombogenicity: Thrombogenicity Assay in Dogs	Pass

Vanguard Dx Biocompatibility Chemical Tests

Tests Performed	Pass / Fail
Infra Red Spectroscopic Analysis (IR Scan)	Pass
USP Physical/Chemical Tests:	
*Non-Volatile Residual	Pass
*Residue on Ignition	Not applicable
*Heavy Metals	Pass
*Buffering Capacity	Pass

As evidenced by the charts above, the Vanguard Dx passed all Biocompatibility tests demonstrating its acceptability for use.

VIII. In-Vitro Testing

An in-vitro study of Vanguard Dx™ catheters was undertaken to assess the functionality, safety, and conformance of Vanguard Dx™ catheter to design requirements and compare its performance to currently manufactured and distributed diagnostic angiographic catheters (Cordis). Tests were conducted December 1, 2004 through December 15, 2004 at Teleflex Medical in Limerick, Ireland.

The following Vanguard Dx™ and control catheter (Cordis) styles were tested: 4 French (Fr) Judkins Right 4.0, 4 Fr Judkins Left 4.0, 4 Fr Pigtail, 5 Fr Judkins Right 4.0, 5 Fr Judkins Left 4.0, and 5 Fr Pigtail.

Vanguard Dx In-Vitro Verification

Tests Performed	Pass / Fail
Dimensional Analysis	Pass
Hub Durability & Compatibility:	
Liquid Leakage	Pass
Air Leakage During Aspiration	Pass
Unscrewing Torque	Pass
Ease of Assembly	Pass
Resistance to Overriding	Pass
Stress Cracking	Pass
Catheter Joint Strength	Pass
Catheter Seal Integrity	Pass
Catheter Burst Pressure	Pass
Flow Characterization	Pass
Catheter Tip Stability	Pass
Restrictor Deformation	Pass
Restrictor Durability	Pass
Guidewire Insertion Force	Pass
Catheter Insertion Force	Pass
Stiffness	Pass
Torquability	Pass
Radiopacity	Pass

As evidenced above, the Vanguard Dx passed all In-Vitro Verification tests demonstrating its acceptability for use.

IX. Shelf Life & Packaging Tests

A study was undertaken to assess the shelf life and packaging validation of Vanguard Dx™ catheters. The tests were also performed to confirm the safety and efficacy of Vanguard Dx™ catheters and its packaging. Testing included accelerated aging, distribution simulation, and catheter performance testing. A currently manufactured and distributed diagnostic angiographic catheter (Cordis) was used as a control. Preconditioning and distribution simulation was conducted at DDL, Inc from October 15 thru December 22, 2004. Catheter performance testing was conducted at Teleflex Medical in Limerick, Ireland from January 15 thru January 20, 2005.

The following Vanguard Dx™ and control catheter styles were tested: 4 French (Fr) Judkins Right 4.0, 4 Fr Judkins Left 4.0, 4 Fr Pigtail, 5 Fr Judkins Right 4.0, 5 Fr Judkins Left 4.0, and 5 Fr Pigtail.

Vanguard Dx Two-Year Shelf Life & Packaging	
Tests Performed	**Pass / Fail**
Pouch Seal Strength	Pass
Pouch Integrity	Pass
Hub Durability & Compatibility:	
Liquid Leakage	Pass
Air Leakage During Aspiration	Pass
Unscrewing Torque	Pass
Ease of Assembly	Pass
Resistance to Overriding	Pass
Stress Cracking	Pass
Catheter Joint Strength	Pass
Catheter Seal Integrity	Pass
Guidewire Insertion Force	Pass
Catheter Burst Pressure	Pass
Catheter Tip Stability	Pass
Restrictor Durability	Pass
Stiffness	Pass
Torquability	Pass

As evidenced above, the Vanguard Dx passed all in-vitro shelf life and packaging tests demonstrating its acceptability for use.

X. PRODUCT COMPARISON CHART

MODEL	MEDRAD *VANGUARD Dx*	CORDIS *INFINITI*
WHERE MARKETED	Intended for Worldwide	Worldwide
TYPE	Angiographic catheter	Angiographic catheter
DISPOSABLE	Yes	Yes
CE MARK (MDD)	Yes	Yes
INDICATIONS	Vanguard Dx is intended for use in the delivery of radiopaque contrast media to selected sites in the vascular system	INFINITI is intended for use in the delivery of radiopaque contrast media to selected sites in the vascular system
DIMENSIONAL		
Catheter Diameter (Fr)	4 & 5	4 & 5
Catheter Usable Lengths	Selective -100cm Flush -110cm	Selective -100cm, Flush -110cm
Catheter Hub	Female Luer	Female Luer
Catheter Shapes	Judkins Left- 3.5, 4.0, 5.0 Judkins Right- 3.5, 4.0 Amplatz Left- 1,2,3 Amplatz Right 1 Internal Mammary Left Coronary Bypass Right Coronary Bypass Multi-purpose A2 Pigtail Angled Pigtail	Judkins Left- 3.5, 4.0, 5.0 Judkins Right- 3.5, 4.0 Amplatz Left- 1,2,3 Amplatz Right 1 Internal Mammary Left Coronary Bypass Right Coronary Bypass Multi-purpose A2 Pigtail Angled Pigtail
Catheter Distal Tip Endhole	4Fr- 0.009" 5Fr- 0.010"	4Fr- 0.040" 5Fr- 0.044"
Maximum allowable Guidewire Size (inches)	4Fr- 0.035" 5Fr- 0.038"	4Fr- 0.038" 5Fr- 0.038"

continued on the next page

PRODUCT COMPARISON CHART (continued from previous page)

MODEL	MEDRAD *VANGUARD Dx*	CORDIS *INFINITI*
PERFORMANCE		
Catheter Rated Burst Pressures	1200 psi (8274 kPA)	1200 psi (8274 kPA)
Catheter Joint Strengths:		
Hub to Shaft	4Fr- 10.9 lbs 5Fr- 12.6 lbs	4Fr- 11.4 lbs 5Fr- 14.7 lbs
Shaft to Soft-Tip	4Fr- 4.7 lbs 5Fr- 7.0 lbs	4Fr- 3.5 lbs 5Fr- 5.4 lbs
Soft-Tip to Atraumatic-Tip	4Fr- 1.7 lbs 5Fr- 2.8 lbs	4Fr- 2.3 lbs 5Fr- 3.0 lbs
Catheter Flow Rates	4Fr Selectives- 13 ml/sec 4Fr Flush- 12.4 ml/sec 5Fr Selectives- 20ml/sec 5Fr Flush- 20ml/sec	4Fr Selectives- 14 ml/sec 4Fr Flush- 4 ml/sec 5Fr Selectives- 20 ml/sec 5Fr Flush- 20 ml/sec
Catheter Tip Stability Selectives (9 centipoise contrast @ 6ml/sec)	4Fr - 1.9 mm 5Fr- 5.4 mm	Greater than 2 cm
Catheter Tip Stability Flush (9 centipoise contrast @ 14ml/sec for 4Fr and 18ml/sec for 5Fr)	4Fr - 1.7 mm 5Fr- 1.7 mm	Not Applicable
Catheter Stiffness	4Fr- 0.173 lbs 5Fr- 0.153 lbs	4Fr- 0.099 lbs 5Fr- 0.139 lbs
Catheter Radiopacity	The tubing is radiopaque for proper visualization under flouroscopy.	The tubing is radiopaque for proper visualization under flouroscopy.
MATERIAL		
Strain Relief Colors	4Fr- Red 5Fr- Grey	4Fr- Blue 5Fr- Blue
Shaft Material	Nylon	Nylon
Soft-Tip Material	Nylon	Nylon
Atraumatic-Tip Material	Nylon	Nylon

NOTE: A statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates only whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As stated by the Commissioner of the FDA, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suit." 42 Fed. Reg. 42, 520.et set. (1977)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 - 2005

Medrad, Inc.
c/o Mr. Geoff M. Fatzinger
Manager Regulatory & Compliance Cardiovascular Strategic Business Unit
One Medrad Drive
Indianola, PA 15051-0780

Re: K050371
Trade/Device Name: Vanguard Dx™ Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: May 18, 2005
Received: May 19, 2005

Dear Mr. Fatzinger:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE K050371

Company: MEDRAD, Inc

Device Name: Vanguard Dx™ angiographic catheter

Indications for Use:

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Contraindications

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)	———

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050371