

K113363

JUN - 6 2012

**Section 5 – 510(k) Summary**

**Submitter:** MEDRAD, INC.  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433-8003 USA

**Contact Person:** Mike Burnside  
Regulatory Affairs Manager  
Phone: (763) 717-1077  
Fax: (763) 780-2227  
Email: micahel.burnside@possis.com

**Date Prepared:** February 16, 2012

**Trade Name:** AngioJet<sup>®</sup> Solent<sup>™</sup> Dista Thrombectomy Set

**Classification:** 870.5150 and 870.1210

**Product Code:** DXE and KRA

**Predicate Device(s):** The subject device is equivalent to the following devices:

- K111182 AngioJet Ultra Solent Omni Thrombectomy Set
- K072769 AngioJet Ultra XMI Thrombectomy Set

**Device Description:** AngioJet Solent Dista Thrombectomy Set is a sterile, single use, disposable set that includes a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Solent Dista Thrombectomy Set is used with the AngioJet Ultra Console.

**Intended Use:** The AngioJet Solent Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

- upper and lower extremity peripheral arteries  $\geq 1.5$ mm in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

**Comparison to predicate:** Design changes were made to the predicate device which included: change in length of device, changes to the jet body, changes to catheter shaft, changes to distal section of catheter, and changes to diameter of catheter.

**Performance Data** Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the following testing:

- Biocompatibility
  - Cytotoxicity (ISO 10993-5)
  - Intracutaneous Reactivity (ISO 10993-10)
  - Sensitization (ISO 10993-10)
  - Acute Systemic Toxicity (ISO 10993-11)
  - Material Mediated Pyrogen (ISO 10993-11)

- Physiochemical (ISO 10993-18)
- Hemocompatibility
  - ASTM Hemolysis (ISO 10993-4)
  - Partial Thromboplastin Time Assay (ASTM F2382-04)
  - C3a Complement Activation (ISO 10993-4)
  - SC5b-9 Complement Activation (ISO 10993-4)
  - Thromboresistance (ISO 10993-4)
- Catheter operational characteristics
- Leak testing
- Corrosion
- Dimensional verification
- Guide wire compatibility tests
- Particulate generation
- Tracking/function in tortuosity
- Extended use
- Clot removal
- Hemolysis
- Thermal dose
- Mechanical integrity (tensile strengths, compression / buckling, torque testing)
- GLP Animal acute and chronic safety studies.

**Conclusion:**

MEDRAD considers the AngioJet Solent Dista Thrombectomy Set to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation. Testing (bench, biocompatibility testing, and animal testing) verified that the new device is substantially equivalent to the predicate devices.



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

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MEDRAD, Inc.  
c/o Mike Burnside  
Regulatory Affairs Manager  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433-8003

Re: K113363

Trade/Device Name: AngioJet Solent Dista Thrombectomy Set  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: DXE, KRA  
Dated: March 28, 2012  
Received: April 11, 2012

Dear Mr. Burnside:

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. However, we remind you 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.

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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" (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 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,



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

**Indications for Use**

510(k) Number (if known): K113363

Device Name: AngioJet® Solent™ Dista Thrombectomy Set

**Indications for Use:**

The AngioJet Solent Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

- upper and lower extremity peripheral arteries  $\geq 1.5$ mm in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

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 IF NEEDED)

*Curtis H. Miller*  
(Division Sign-Off) of CDRH, Office of Device Evaluation (ODE)  
Division of Cardiovascular Devices

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