Section 5 – 510(k) Summary

FEB 14 2014

Submitter:	MEDRAD, INC. 9055 Evergreen Boulevard NW Minneapolis, MN 55433-8003 USA
Contact Person:	George Lucas Sr. Regulatory Affairs Associate Phone: (763) 450-8060 Fax: (763) 780-2227 Email: george.lucas@bayer.com
Date Prepared:	November 25, 2013
Trade Name:	AngioJet® Ultra AVX® Thrombectomy Set
Classification:	870.5150
Product Code:	DXE
Predicate Device(s):	The subject device is equivalent to the following device: • K082382 AngioJet Ultra AVX Thrombectomy Set
Device Description:	AngioJet Ultra AVX Thrombectomy Set is a sterile, single use, disposable set that includes a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Ultra AVX Thrombectomy Set is used with the AngioJet Ultra Console.
Intended Use:	AngioJet Ultra AVX Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from A-V Access conduits ≥ 3 mm in diameter.
Comparison to predicate:	Change to the color of the manifold from yellow to smoke grey. In addition, design changes were made to the predicate device that included: change in waste bag tubing, change in bubble trap, change in glue for manifold bonds, change in manifold strain relief, and change in waste bag to tube connection.

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 Testing
  - Cytotoxicity (ISO 10993-5)
  - Sensitization (ISO 10993-10)
  - Intracutaneous Reactivity (ISO 10993-10)
  - Acute Systemic Toxicity (ISO 10993-11)
  - ASTM Hemolysis (ISO 10993-4)
  - Material Mediated Pyrogen (ISO 10993-11)
  - Physiochemical (ISO 10993-18)
- Design Verification Testing at zero time and at 2 years of accelerated aging.
  - Operation Pressure
  - Net Evacuation
  - Infusion rate
  - Extended Use
  - Dimensional testing
  - System leak testing
  - Contrast Injection
  - Guide Wire Passage
  - Mechanical Integrity testing

Conclusion:

MEDRAD considers the AngioJet Ultra AVX Thrombectomy Set to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.

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

February 14, 2014

MEDRAD, Inc.
Mr. George Lucas
Senior Regulatory Affairs Associate
9055 Evergreen Blvd., N.W.
Minneapolis, MN 55433-8003

Re: K133629
Trade/Device Name: AngioJet Ultra AVX Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: January 14, 2014
Received: January 15, 2014

Dear Mr. Lucas,

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 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. 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,

Kenneth J. Cavanaugh -S

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

Enclosure

K133629

Indications for Use

510(k) Number (if known): _____

Device Name: AngioJet® Ultra AVX® Thrombectomy Set

Indications for Use:

The AngioJet Ultra AVX Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from A-V access conduits ≥ 3 mm in diameter.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S