

APR 10 2013**510(k) SUMMARY****General Information:**

Date of Summary Preparation: April 8, 2013

Name and Address of Manufacturer: MEDRAD, Inc.
9055 Evergreen BLVD NW
Minneapolis, MN 55433-8003

Contact Person: Brit Baird
Director of Regulatory Affairs
Phone: 425-636-4137
Fax: 425-636-4198

Device Trade Names: JETSTREAM® XC 2.4/3.4 System
JETSTREAM® XC 2.1/3.0 System
JETSTREAM® SC 1.85 System
JETSTREAM® SC 1.6 System

Common Name: Peripheral Atherectomy Catheter

Regulation Number: 21 CFR 870.4875

Regulation Name: Intraluminal Artery Stripper

Regulatory Class: Class II

Classification Panel: Cardiovascular

Product Code: MCW

Performance Standards: Performance Standards do not currently exist for these devices. None are established under Section 514.

Device Description: The Jetstream Systems are rotational atherectomy catheter systems designed with either a fixed (Jetstream SC 1.85, Jetstream SC 1.6) or an expandable (Jetstream XC 2.4/3.4, Jetstream XC 2.1/3.0) cutting tip intended for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through a port in the Catheter tip to an external collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

The Jetstream Systems consist of two primary components: a Catheter with Control Pod and a Console, which are packaged separately. Each of these system components is described generally as follows:

- **Jetstream Catheter with Control Pod:** A sterile, single-use unit consisting of an electrically-driven Catheter with attached Control Pod. As with the predicate device, the modified Jetstream Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities and the Control Pod with Activation Handle provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a single pouched tray.
- **PV Console:** A reusable compact PV Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The PV Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

The primary modification of this 510(k) is a redesign of the Control Pod and Activation Handle, which improves the user interface. This modification applies to the entire family of Jetstream Systems.

Indications for Use: The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Substantially Equivalent Devices: MEDRAD cites the following devices as the primary predicate devices for the aforementioned modification and substantial equivalence basis.

| Primary Predicate Devices | Pathway Medical Predicate 510(k) |
|-----------------------------|----------------------------------|
| JETSTREAM Navitus® L System | K122916 |
| JETSTREAM Navitus® System | |
| JETSTREAM G3® SF System | |
| JETSTREAM G3® SF 1.6 System | |

However, the design rationale for and device testing of the modified devices also includes references to the additional predicate devices listed in the table below:

| Other Predicate Devices | Pathway Medical Predicate 510(k) |
|--|----------------------------------|
| JETSTREAM Navitus® L System | K120242 |
| JETSTREAM G3® SF 1.6 System | K111229 |
| JETSTREAM Navitus® System | K110626 |
| JETSTREAM G3® SF System | K101334 |
| JETSTREAM G3® System | K101221 |
| JETSTREAM G3® System | K093456 |
| JETSTREAM G3® System | K092332 |
| JETSTREAM G2™ NXT System | K091509 |
| JETSTREAM Pathway PV™ Atherectomy System | K082186 |
| Pathway PV™ Atherectomy System | K081328 |

Testing Summary: To demonstrate substantial equivalence of the modified Jetstream Systems to the predicate Jetstream Systems, the technological and performance characteristics were evaluated by completion of the following testing:

- Dimensional Verification
- Heat Generation
- System Reliability/Life Test
- Aspiration Efficiency & Crossing Time
- Speed Drop – Flexibility
- Material Liberation (Guidewire Teflon and Stainless Steel)
- Rotational Speed
- Accessory Compatibility
- Infusion & Aspiration Flow Rates
- Catheter Pull
- Catheter Trackability and Pushability
- Torque to Failure
- Catheter Burst
- Cable pull
- Pod weight
- Visual/surface inspection
- Pod Logic

- Auditory Feedback
- Packaging and Shelf Life
- Sterilization Validation
- Guidewire Management
- Electrical Safety (UL 60601-1 and EN/IEC 60601-1 (2nd Edition))
 - Durability of Markings
 - Power Input Test
 - Determination of Applied Parts and Accessible Parts
 - Leakage Current (Before and After Humidity)
 - Dielectric Strength Test
 - Mechanical Strength
 - Normal Temperature Test
 - Mechanical Strength and Resistance to Heat
 - Insulation
- EMC (IEC 60601-1-2)
 - Radiated Emissions
 - Electrostatic Discharge (ESD)
 - Radiated Immunity
 - Magnetic Field Immunity
- Biocompatibility
 - Cytotoxicity (MEM Elution)
 - Hemolysis (Direct Contact)
 - Hemolysis (Extraction)
 - Acute Systemic Toxicity (2 extracts – saline & CSO)
 - Intracutaneous Reactivity (2 extracts – saline & CSO)
 - Sensitization (Kligman Maximization method)
 - Pyrogenicity (Material Mediated)
 - Partial Thromboplastin Time (PTT)
 - Complement Activation (C3a and SC5b-9)

The results from these tests:

- demonstrate that the technological and performance characteristics of the modified Jetstream Systems are comparable to the predicate Jetstream Systems,
- support the safety and effectiveness of the modification that is the subject of this 510(k), and
- ensure the modified devices can perform in a manner equivalent to the predicate Jetstream Systems with the identical intended use.

Conclusion (Statement of Equivalence): The data and information presented within this submission (including *in vitro* bench testing) and the similarities between the modified and predicate devices support a determination of substantial equivalence, and therefore market clearance of the modified Jetstream Systems through this 510(k) Premarket Notification.



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

April 10, 2013

MEDRAD, Inc.
c/o Mr. Brit Baird
Director of Regulatory Affairs
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K130637

Trade/Device Name: Jetstream XC 2.4/3.4 System
Jetstream XC 2.1/3.0 System
Jetstream SC 1.85 System
Jetstream SC 1.6 System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: March 11, 2013
Received: March 12, 2013

Dear Mr. Baird:

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.

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" (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,

Matthew  Hillebrenner

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

