May 20, 2021

MEDRAD Interventional/Possis
Doug Atkins
Sr Regulator Affairs Specialist
9055 Evergreen Blvd., NW
Minneapolis, Minnesota 55433-8003

Re: K090253
Trade/Device Name: AngioJet Ultra DVX And Xpeedior Thrombectomy Sets
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Doug Atkins:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 8, 2009. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.05.20 09:37:08 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDRAD Interventional/Possis
c/o Mr. Doug Atkins
Senior Regulatory Affairs Associate
9055 Evergreen Blvd. NW
Minneapolis, MN 55433-8003

APR - 8 2009

Re: K090253
Trade/Device Name: AngioJet Ultra DVX Thrombectomy Set
and AngioJet Xpeedior Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: January 30, 2009
Received: February 2, 2009

Dear Mr. Atkins:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. J. Hillebrenner

for Bram D. 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): K090253

Device Name: AngioJet® Ultra DVX® Thrombectomy Set

Indications for Use:

The AngioJet Ultra DVX Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from

- Upper and Lower extremity peripheral arteries ≥ 3 mm in diameter
- Upper extremity peripheral veins ≥ 3 mm in diameter
- Ileofemoral and lower extremity veins ≥ 3 mm in diameter
- AV access conduits ≥ 3 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___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

M. D. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090253

Indications for Use

510(k) Number (if known): K090253

Device Name: AngioJet® Ultra Xpeedior® Thrombectomy Set

Indications for Use:

The AngioJet Ultra Xpeedior Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from

- Upper and Lower extremity peripheral arteries ≥ 3 mm in diameter
- Upper extremity peripheral veins ≥ 3 mm in diameter
- Ileofemoral and lower extremity veins ≥ 3 mm in diameter
- AV access conduits ≥ 3 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090253

APR - 8 2009

5. 510(k) Summary

Submitter: MEDRAD Interventional / Possis
(MIP)9055 Evergreen Boulevard, N.W.
Coon Rapids, MN 55433

Contact Person: Doug Atkins
Sr. Regulatory Affairs Associate
Phone: 763.450-8060
Fax: 763.780.2227
Email: doug.atkins@possis.com

Device Common Name: Embolectomy Catheter

Device Trade Name: AngioJet® Ultra DVX® Thrombectomy Set and
AngioJet® Ultra Xpeedior® Thrombectomy Set

Device Classification Name: Embolectomy Catheter

Predicate Devices:
AngioJet AVX Thrombectomy Set with injection (K082382)
AngioJet Ultra DVX Thrombectomy Set (K072269)
AngioJet Ultra Xpeedior Thrombectomy Set (K071342)
AngioJet Xpeedior Rheolytic Thrombectomy Catheter (K071336)
AngioJet Xpeedior Rheolytic Thrombectomy Catheter (K071514)
AngioJet Xpeedior Catheter (K993564)
AngioJet LF140 Catheter (K960970)

Device Description

AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are sterile, single use, disposable sets that include the AngioJet DVX and Xpeedior Thrombectomy catheters and a pump in one combined unit. The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are used with the AngioJet Ultra Console. A 3-port catheter manifold is used, so that contrast media and other fluids can be injected into the bloodstream where the catheter is positioned.

Indications for Use
The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from the:

- Upper and Lower extremity peripheral arteries ≥ 3 mm in diameter
- Upper extremity peripheral veins ≥ 3 mm in diameter
- Ileofemoral and lower extremity veins ≥ 3 mm in diameter
- AV access conduits ≥ 3 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 Devices
MEDRAD Interventional / Possis (MIP) considers the AngioJet Ultra DVX and Xpeedior Thrombectomy Sets 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.

Supporting Information
Bench and biocompatibility testing supported using a 3-port catheter manifold and adding labeling instructions for using the AngioJet Ultra DVX and Xpeedior Thrombectomy Set to inject contrast media and other fluids into the bloodstream where the catheter is positioned.