September 15, 2021

Possis Medical, Inc.
Mike Burnside
Sr. Regulatory Affairs Associate
9055 Evergreen Blvd., N.w.
Minneapolis, Minnesota 55433-8003

Re: K072269
Trade/Device Name: Angiojet Ultra DVX Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Mike Burnside:

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 September 28, 2007. 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: 2021.09.15 10:22:47 -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

SEP 2 8 2007

Mr. Mike Burnside
Sr. Regulatory Affairs Associate
Possis Medical, Inc.
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K072269
Trade/Device Name: AngioJet Ultra DVX Thrombectomy Set, Model 106552
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: August 10, 2007
Received: August 15, 2007

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.

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K072269

Device Name: AngioJet® Ultra DVX® Thrombectomy Set

Indications for Use:

The AngioJet Ultra DVX Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from upper and lower extremity peripheral arteries ≥3 mm in diameter; break apart and remove thrombus from upper extremity and infra-inguinal lower extremity peripheral veins ≥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)

Donna R. Vodenos
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072269

K072269

Section 5 – 510(k) Summary

SEP 28 2007

Submitter:	Possis Medical, Inc. 9055 Evergreen Boulevard NW Minneapolis, MN 55433-8003 USA
Contact Person:	Mike Burnside Sr. Regulatory Affairs Associate Phone: (763) 780-4555 Fax: (763) 780-2227 Email: mike.burnside@possis.com
Date Prepared:	August 10, 2007
Trade Name:	AngioJet® Ultra DVX® Thrombectomy Set
Classification:	870.5150 and 870.1210
Product Code:	DXE and KRA
Predicate Device(s):	The subject devices are equivalent to the following devices: • K071342 AngioJet Ultra XPEEDIOR Thrombectomy Set • K071514 AngioJet XPEEDIOR® 120 Catheter • K052256 and K061951- AngioJet XPEEDIOR® 120 Catheter • K050794 - AngioJet DVX Rheolytic Thrombectomy Catheter
Device Description:	Each AngioJet Ultra DVX Thrombectomy Set is a sterile, single use, disposable set that includes the Thrombectomy Catheter and Pump in one combined unit. The AngioJet Ultra DVX Thrombectomy Set is used with the AngioJet Ultra Console.
Intended Use:	The AngioJet Ultra DVX Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from upper and lower extremity peripheral arteries ≥3 mm in diameter; break apart and remove thrombus from upper extremity and infra-inguinal lower extremity peripheral veins ≥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.
Functional and Safety Testing:	Representative samples of the devices underwent bench testing, including but not limited to mechanical testing, biocompatibility, sterility, comparative testing to demonstrate appropriate functional and performance characteristics.
Conclusion:	Possis Medical, Inc. considers the AngioJet Ultra DVX 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.