October 8, 2021

Possis Medical, Inc.
Mark Stenoien
Manager, Clinical & RA
9055 Evergreen Blvd., N.w.
Minneapolis, Minnesota 55433-8003

Re: K050794
Trade/Device Name: Angiojet DVX Rheolytic Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Mark Stenoien:

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 28, 2005. 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: 2021.10.08 10:36:15 -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

APR 28 2005

Possis Medical, Inc.
c/o Mr. Mark Stenoien
Manager, Clinical & Regulatory Affairs
9055 Evergreen Blvd. N.W.
Minneapolis, MN 55433

Re: K050794
AngioJet® DVX™ Rheolytic™ Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (Two)
Product Code: DXE
Dated: March 28, 2005
Received: March 29, 2005

Dear Mr. Stenoien:

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.

1

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 Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmer

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

Enclosure

Indications for Use Page

510(k) Number (if known): K050794

Device Name: AngioJet® DVX™ Rheolytic™ Thrombectomy Catheter

Indications for Use:

The AngioJet DVX Rheolytic Thrombectomy Catheter is intended for use with the AngioJet System in breaking apart and removing thrombus from infra-inguinal peripheral arteries ≥ 3 mm in diameter.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ (Per 21 CFR 801.109) Or Over-the-Counter Use ____

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050794

K050794
1 of 1

APR 2 8 2005

510(k) Summary

Submitter:	Possis Medical, Inc. 9055 Evergreen Blvd. N.W. Minneapolis, MN 55433 USA
Contact Person:	Mr. James Gustafson Vice President, Research, Development & Engineering Possis Medical, Inc. 9055 Evergreen Blvd. N.W. Minneapolis, MN 55433 USA Phone: (763) 780-4555 Fax: (763) 780-2227 Email: jgustafson@Possis.com
Date Prepared:	March 28, 2005
Trade Name:	AngioJet® DVX™ Rheolytic™ Thrombectomy Catheter
Classification Name and No.	21 CFR 870.5150 Embolectomy Catheter –Class II
Product Code:	DXE
Predicate Device	AngioJet XPEEDIOR® 120 Catheter under K040013 on 5/18/2004.
Device Description:	The AngioJet DVX Catheter is a 90 cm, 6 French, sterile, single-use catheter designed for removing thrombus from vascular conduits. High velocity saline jets directed back into the Catheter create a localized low-pressure zone at the distal tip (Bernoulli effect) that results in suction, break-up, and removal of thrombus through the exhaust lumen. The Catheter is designed to track over a 0.035" guide wire and through an 8 French high flow guide catheter (0.086 inch minimum internal diameter), which allows sufficient passage of the Catheter with adequate clearance for injection of standard contrast media, if desired.
Intended Use:	The AngioJet DVX Rheolytic Thrombectomy Catheter is indicated for use with the AngioJet System in breaking apart and removing thrombus from infra-inguinal peripheral arteries ≥ 3mm in diameter.
Statement of Technological Comparison	The subject device have the following similarities: • The same indication for use; • The same operating principle; • The same basic design; • The same manufacturing environment; • The same sterilization process; and • The same packaging configurations. In summary, the AngioJet DVX Catheter, as described in this submission is, in the opinion of Possis Medical Inc., substantially equivalent to the predicate device.
Conclusion:	The AngioJet DVX Catheter, as described in this submission, is substantially equivalent to the predicate device, the XPEEDIOR 120 Catheter K040013. This conclusion is based upon the similarities of the devices in terms of functional design, indication for use, principles of operation, materials, and performance characteristics.