October 8, 2021

Possis Medical, Inc.
James Gustafson
V.P. Of Quality Systems And Reg./clinical Affairs
9055 Evergreen Blvd., N.w.
Minneapolis, Minnesota 55433-8003

Re: K972610
Trade/Device Name: AngioJet Rapid Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear James Gustafson:

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 11, 2000. 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 10:39:45 -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 11 2000

Mr. James D. Gustafson
Possis Medical, Inc.
9055 Evergreen Boulevard NW
Minneapolis, MN 55433

Re: K972610
AngioJet® LF140 Rheolytic Thrombectomy
Regulatory Class: II (two)
Product Code: DXE
Dated: February 28, 2000
Received: February 29, 2000

Dear Mr. Gustafson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Electronic Product Radiation Control provisions, or other Federal laws or regulations. This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ANGIOJET® LF140 CATHETER
INDICATION FOR USE STATEMENT

FEBRUARY 2000

The AngioJet System, with the Catheter, is intended for breaking apart and removing thrombotic obstructions from infra-inguinal peripheral arteries ≥ 2.0 mm in diameter.

Christy M. Ahn for Dillard

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972610

APR 1 1 2000

K972610

ANGIOJET™
eolytic™ thrombectomy system

POSSIS ANGIOJET RAPID THROMBECTOMY SYSTEM
510(K) SUMMARY

SUBMITTER INFORMATION

SUBMITTER NAME	Possis Medical, Inc. (PMI)
ADDRESS	9055 Evergreen Boulevard NW Minneapolis, MN 55433
PHONE NUMBER	(612) 780-4555
FAX NUMBER	(612) 780-2227
CONTACT	Primary James D. Gustafson Vice President of Quality Systems and Regulatory/Clinical Affairs Alternate Timothy J. Kappers Supervisor, Regulatory Affairs & Compliance
SUMMARY DATE	February 28, 2000

DEVICE NAMES

TRADE NAME	Possis AngioJet Rapid Thrombectomy Catheter: LF140 Catheter, Model 3040C
COMMON NAME	Embolectomy / Thrombectomy Catheter
CLASSIFICATION NAME	Embolectomy Catheter (21 CFR 870.5150)
LEGALLY MARKETED PREDICATE DEVICES	Fogarty Arterial Embolectomy Catheter Baxter Healthcare Corp., Edwards U.S. Division (Pre-1976 device) Applied Vascular Arterial Embolectomy Catheter Applied Vascular Devices, Inc. K901627 Possis AngioJet Rapid Thrombectomy Catheters Possis Medical, Inc. K960970

Possis Medical, Inc.
9055 Evergreen Boulevard NW, Minneapolis, MN 55433-8003 phone: 612.780.4555 fax: 612.783.8463 toll free: 800.810.7677

POSSIS MEDICAL INC

DEVICE DESCRIPTION:

The AngioJet Rheolytic Thrombectomy System consists of a single-use Catheter, single-use Pump Set, and multi-use Drive Unit. The same Drive Unit and Pump Set are compatible with various Catheters with different design features.

The Catheter tracks and operates over a guide wire and is introduced through a guide catheter. It may be operated only in conjunction with the Pump Set and Drive Unit. Catheter components include a manifold, shaft, and tip segments. The manifold contains connections for the high pressure saline supply and effluent removal lines on the Pump Set, and a hemostasis valve for sealing around the guide wire. The Catheter shaft is dual lumen: one lumen provides high pressure saline delivered to the Catheter tip through a stainless steel hypodermic tube; the other larger lumen is used for evacuation of thrombotic debris and for guide wire passage. The Catheter tip is a stainless steel sub-assembly through which the stainless steel hypodermic tubing extends and terminates distally in a closed loop. The loop contains proximally directed jet orifices aimed at the evacuation lumen entrance.

Thrombectomy is accomplished with the introduction of a pressurized saline jet stream through the directed orifices in the Catheter distal tip. The jets generate a localized low pressure zone via the Bernoulli effect, which entrains and macerates thrombus. The same jets also provide the dynamic pressure to drive thrombotic debris down the exhaust lumen of the Catheter and out of the body for disposal.

INTENDED USE:

The AngioJet System, with the Catheter, is intended for breaking apart and removing thrombotic obstructions from infra-inguinal peripheral arteries $\geq$ 2.0 mm in diameter.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The AngioJet LF140 Catheter is the subject of the present 510(k) and is identical to the Catheter model cleared under K960970. The AngioJet Catheter and Fogarty-type embolectomy / thrombectomy catheters share the following characteristics: both are Catheter mediated methods for mechanical thrombectomy. The diameter of the AngioJet Catheter is within the range of diameters available for the predicate device. Both the AngioJet Catheter and the predicate devices are constructed of steel and plastic materials, and are sterile, one time use class II medical devices.

The only technology difference between the AngioJet Catheter and the predicate devices is in the method that each uses to achieve mechanical thrombectomy. The Fogarty-type catheters use mechanical dislodgment and isolation to achieve thrombectomy. Using surgical introduction, the Fogarty-type device is advanced through the target lesion proximal to distal. The balloon at the distal tip is inflated with a suitable medium and the Catheter is dragged out of the vessel. The inflated

balloon is occlusive inside the vessel lumen so the thrombus is dislodged and removed from the body through the access site.

By comparison, the AngioJet Drive Unit and Pump Set deliver a high-velocity stream of sterile saline through the hypotube to the distal tip of the Catheter. The saline exits the Catheter through holes which direct the stream of saline past a small open space and into the mouth of the exhaust lumen of the Catheter. These high-velocity saline jets create a venturi effect which produces a local area of very low pressure around the Catheter tip, which attracts thrombus into the region of high velocity jets, which in turn disassociate the thrombus into small particles and propel the debris down the effluent lumen of Catheter and out of the patient's body. The AngioJet Catheter is introduced percutaneously and advanced over a guidewire to the target lesion. The Catheter may be operated in the target vessel proximal to distal or distal to proximal.

SUMMARY OF CLINICAL RESULTS

The AngioJet LF140 Catheter has already been proven safe and effective in the treatment of patients with coronary thrombus. For peripheral arterial thrombus, an analysis was performed comparing clinical results from a prospective non-randomized cohort of patients treated with AngioJet for peripheral arterial thrombus to clinical results reported in the literature for a similar group of patients treated with standard intra-arterial infusion of urokinase.

AngioJet treatment resulted in a higher reported effectiveness for its primary function of thrombus removal (complete thrombus removal not requiring additional intervention to treat thrombus). A lower percentage of patients using AngioJet reported distal embolization events requiring additional thrombectomy aspiration or local thrombolytic intervention. Any dissection or vessel perforation that occurred in the AngioJet group was minor, without clinical sequelae.

The AngioJet study group also had dramatically fewer deaths (less than 50% of that reported for the urokinase group), higher amputation-free survival, and higher primary patency than the urokinase group, at both six and twelve month follow-up.

The analysis concluded that there was no evidence to suggest that either the frequency or severity of procedure-related complications were higher with use of AngioJet than with urokinase, and that one-year follow-up data suggests no increased risk of death, amputation, or loss of patency due to AngioJet treatment over that seen in patients treated with urokinase.

The results from this comparison are sufficient evidence to support an expansion of the indication for use of the AngioJet LF140 Catheter to include the treatment of thrombus in peripheral arteries and arterial conduits.