

APR 28 2000

K993564

**ANGIOJET® XPEEDIOR™ CATHETER
510(K) SUMMARY**

APRIL 2000

**SUBMITTER'S
INFORMATION**

Possis Medical, Inc.
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CONTACT

Primary

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Supervisor, Regulatory Affairs & Compliance

Alternate

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SUMMARY DATE

April 18, 2000

DEVICE TRADE NAME

AngioJet XPEEDIOR Catheter

COMMON NAME

Thrombectomy/Embolectomy Catheter

DEVICE CLASS

Class II

**LEGALLY MARKETED
PREDICATE DEVICE**

AngioJet LF140 Catheter

DEVICE DESCRIPTION

The AngioJet XPEEDIOR Catheter is designed for operation with the AngioJet Rheolytic™ Thrombectomy System (AngioJet System). The AngioJet System consists of three components: the Drive Unit, disposable Pump Set, and disposable Catheter.

The AngioJet XPEEDIOR Catheter is a new AngioJet catheter model which has been designed to optimize clot removal performance. As with other AngioJet Catheter models the XPEEDIOR Catheter consists of a manifold, Catheter body, and tip. The manifold contains connections for the high pressure saline supply, an exhaust removal line, and a hemostasis valve for sealing around an 0.035" and smaller diameter guidewire. The Catheter body consists of a stainless steel hypodermic tube extending the length of the catheter which carries high pressure saline to the tip. This tube lies within a single lumen polymeric tube which serves as a lumen for both exhaust and guidewire. The tip contains the portion of the hypotube which has been formed into a toroidal loop. Six small holes are located on the proximal portion of the loop. Jets of saline exit these holes at high velocity and are directed proximally from the tip. These jets flow past a primary set of orifices in the exhaust tube referred to as inflow windows. Thrombus is entrained (via the Bernoulli effect of high velocity creating a vacuum) into these windows and then macerated. The thrombotic debris is propelled by the dynamic pressure of the jets through the exhaust lumen and out of the manifold body to the exhaust bag. A set of secondary orifices referred to as outflow windows are positioned in the exhaust tube proximal to the inflow windows. These aid in recirculating and breaking up the thrombus. The outflow windows are the primary new feature compared to previous AngioJet Catheter models except for the F105, in which 3 low-pressure, radially directed jets were employed. Fluid, which is powered by the dynamic pressure of the jets, flows from these outflow windows and then back to the inflow windows. This recirculation pattern improves the efficacy of the device by increasing the volume of the entrainment zone while still maintaining a minimal catheter profile.

INTENDED USE

The AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter is intended for breaking apart and removing thrombus from A-V access conduits when used with the AngioJet System.

COMPARISON TO PREDICATE DEVICE

Table 1 summarizes key technical characteristics and physical properties of the AngioJet XPEEDIOR Catheter and the predicate device (the AngioJet LF140 Catheter).

TABLE 1
Comparison of Technical Characteristics

	LF140 Catheter	XPEEDIOR Catheter
Application	Thrombus removal in AV access grafts	Thrombus removal in AV access grafts
Intended Guidewire	0.018"	0.035"
Materials	Same	Same
Working Length	140cm	60cm
Maximum Shaft Diameter	5 Fr	6 Fr
Flexibility	Enhanced	Standard
Exhaust Tubing	6333 Dual Lumen Pebax	5333 Single Lumen Pebax
Tip Style	Stainless Steel Cap	Polymeric Tapered Flexible
Gap length	0.018"	gap replaced with inflow and outflow windows
Drive Unit Operating Mode	Mode 2- 50cc/min	Mode 1- 60cc/min
Number of Jets	6	6
Operating Pressure	7-12 Kpsi	7-12 Kpsi

NON-CLINICAL TESTS

Extensive *in vitro*, physical, functional, animal, and biocompatibility tests have been performed on the XPEEDIOR Catheter. These tests have shown that the XPEEDIOR Catheter performs comparably to the predicate device. All performance results for the XPEEDIOR Catheter and the predicate device exceed physiological requirements for the intended clinical use of the device.

CONCLUSION

The AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter is intended for breaking apart and removing thrombus from A-V access conduits when used with the AngioJet System. The present 510(k) compares the XPEEDIOR Catheter to a legally marketed predicate device. The intended use, catheter configuration, material, labeling, method of use, intended anatomical sites, and the target population of the XPEEDIOR Catheter are the same as those of the predicate device.

There are no significant technological differences between the subject device and the predicate device.

As summarized above, this 510(k) notification provides adequate information to support a determination of substantial equivalence between the XPEEDIOR Catheter and its predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Timothy J. Kappers
Supervisor, Regulatory Affairs & Compliance
Possis Medical, Inc.
9055 Evergreen Boulevard N.W.
Minneapolis, MN 55433

Re: K993564
Possis AngioJet® X-STREAM™ Rheolytic Thrombectomy Catheter
Regulatory Class: II (two)
Product Code: MCW
Dated: February 3, 2000
Received: February 4, 2000

Dear Mr. Kappers:

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 (Pre-market 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 pre-market 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.

Page 2 - Mr. Timothy J. Kappers

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® XPEEDIOR™ CATHETER
INDICATION FOR USE STATEMENT**

APRIL 00

The AngioJet XPEEDIOR Rheolytic™ Thrombectomy Catheter is intended for breaking apart and removing thrombus from A-V access conduits when used with the AngioJet System.

Christopher M. McFarland

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993564