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Possis AngioJet® Rapid Thrombectomy System
510(k) SUMMARY

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1. Submitter Information

Submitter Name:	Possis Medical, Inc.
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Summary Date:	22 November 1996

2. Device Names:

Trade Name:	Possis AngioJet® Rapid Thrombectomy System Possis AngioJet F105 Catheter, Model 3030C Possis AngioJet LF140 Catheter, Model 3040C Possis AngioJet Pump Set, Model 3020P Possis AngioJet Drive Unit, Model 3000A
Common Name:	Embolectomy Catheter Thrombectomy Catheter
Classification Name:	Embolectomy Catheter (21 CFR 870.5150)

3. Legally Marketed Predicate Devices:

Applied Vascular Arterial Embolectomy Catheter
Applied Vascular Devices, Inc.
K901627

Fogarty® Arterial Embolectomy Catheter
Baxter Healthcare Corp., Edwards U.S. Division
(pre-1976 device)

4. Device Description:

The AngioJet Rapid Thrombectomy System consists of three components: the Drive Unit, disposable Pump Set, and disposable Catheter. Currently, two Catheter models are available. The present 510(k) seeks market clearance for these components, and other future Catheter models as described below.

AngioJet Catheter: The single use AngioJet Catheter consists of a manifold, Catheter body, and tip. The manifold contains connections for the high pressure saline supply and effluent removal lines and a hemostasis valve for sealing around a 0.014-0.018 inch diameter guide wire. A stainless steel hypodermic tube extends the length of the Catheter to carry high pressure saline to the distal tip. This tube is located in one lumen of a two-lumen plastic tube. The other, larger lumen in the plastic tube is used for evacuation of the lysed thrombus and for passage of the guide wire.

The Catheter tip is a stainless steel subassembly through which the stainless steel hypodermic tube extends and terminates in a loop. This loop features proximally-directed jet orifices, aimed at the evacuation lumen entrance. In addition to their effect in breaking up thrombus, these jets provide the dynamic pressure to drive thrombotic debris down the exhaust lumen of the Catheter.

The two current Catheter models have several different features, as identified below. The F105 was the original design. The LF140 was developed to ease treatment of very distal lesions accessed through more tortuous anatomy. The table below compares the two models.

	F105	LF140
Drive Unit Mode Setting	Mode 1	Mode 2
Working Length	105 cm	140 cm
Maximum Shaft Diameter	5 French	5 French
Distal Shaft Taper	None	4-3.5 French
Flexibility	Standard	Enhanced
Stainless Steel Tip	5 French	5 French
Tip Cap	No	Yes
Intended Guidewire	.018 inch	.014-.018 inch
Jets	3 high-pressure, proximally directed 3 low-pressure, radially directed	6 high pressure, proximally directed

AngioJet Pump Set: The single use Pump Set consists of a high pressure saline supply line, a high pressure pulsatile pump, an effluent evacuation line, and an effluent collection bag. The pulsatile pump is a stainless steel assembly capable of functioning over a range of ~0 to at least 15,000 psi; however, the Drive Unit controls the pump operation in the range of approximately 7,000 to 12,000 psi. (This refers to the peak pressure; the pump is pulsatile, and therefore operates from zero pressure between pulses up to this maximum pressure during the pump stroke.)

Saline is supplied to the pump from a standard intravenous saline bag accessed with a cannula and a length of plastic tubing (the low pressure supply line) attached to the pump. A bubble trap is located in this line. A 7-foot high pressure supply line consisting of stainless steel tubing encased

in one lumen of a dual-luman plastic tube terminates with a high pressure quick connect nut. The other lumen of the dual-luman tube attaches to the Catheter manifold through a luer connection and is used to carry effluent away from the Catheter to a collection bag hung on the side of the Drive Unit.

AngioJet Drive Unit: This component generates the forces and motions necessary to operate the Catheter. The Drive Unit is built into a mobile cart. All mechanical and electrical components needed for operating and controlling the Drive Unit are contained within the cart, with the exception of a foot switch which the operator uses to activate the system and perform the thrombectomy. Drive Unit controls are contained in a membrane switch control panel.

The force and motion for driving the high pressure pump is generated by means of an electronically-controlled, motor-driven mechanism. A peristaltic pump is located on the Drive Unit for the purpose of controlling the removal rate of thrombotic debris-containing effluent.

The Drive Unit is designed to accommodate three Mode settings (of which two are currently available), each appropriate to specific Catheter model(s).

The Drive Unit incorporates a series of safety alarms to ensure the proper flow of fluids to and from the patient. This includes a flow sensor/bubble detector on the low pressure supply between the saline bag and the high pressure pump, a flow sensor/bubble detector on the effluent line just upstream of the peristaltic pump, a motion sensor to detect proper operation of the peristaltic pump, a pressure sensor to ensure proper performance of the high pressure disposable pump, and sensors to detect the presence of a properly primed high pressure pump. Also included are sensors to detect that the pump bay (the recess on the Drive Unit into which the pump is loaded) is not blocked, that rear cabinet doors are closed, and that the effluent tubing is properly loaded in the peristaltic pump. These functions are controlled from a logic control board located within the Drive Unit. Activation of any of these sensors will prevent the Drive Unit from operating if the proper conditions for safe operation are not met. Status of the safety alarms is displayed on the control panel.

5. Intended Use

The Possis AngioJet Rapid Thrombectomy System is intended for breaking apart and removing unorganized thrombus from A-V access grafts.

6. Summary of Technological Characteristics

The Possis AngioJet Rapid Thrombectomy System and Fogarty-type embolectomy/thrombectomy catheters share these technical characteristics: both are catheter-mediated methods of mechanical thrombectomy. The diameter of the AngioJet Catheter is within the range of diameters available for the predicate device. Both the AngioJet Catheter and its predicate are constructed of steel and plastic materials. Both catheters are sterile, one-time-use Class II medical devices.

The single significant technological difference between the AngioJet system and its predicate device is in the details of how each achieves mechanical thrombectomy.

Fogarty-type catheters employ mechanical dislodgment and dislocation to achieve thrombectomy. Using surgical introduction, the device is advanced through the target lesion proximal to distal. The balloon at the distal tip is inflated with an appropriate medium (e.g., saline, CO_2), and the catheter is then pulled back out of the vessel. The balloon is occlusive within the vessel lumen, so thrombus is dislodged and pulled out through the surgical access site ahead of the balloon tip.

The AngioJet Drive Unit and Pump Set deliver a high-velocity stream of saline to the distal tip of the Catheter, where it exits through holes which direct it past a small open space and into the mouth of the exhaust lumen of the Catheter. This transit of high-velocity saline jets creates venturi forces which produce a local area of negative pressure around the Catheter tip, which entrains unorganized thrombus, disassociates it into small particles, and evacuates the resulting debris from the body.

The AngioJet Catheter is introduced percutaneously and advanced over a guidewire to the target lesion. Catheter passage through the thrombus to effect thrombectomy may be made proximal to distal, or distal to proximal.

7. Discussion of Non-Clinical Tests

The development of the AngioJet System involved physical, functional, biocompatibility, and animal tests to validate the design and function of the system and its equivalence to its predicate device. These are summarized below.

Physical testing of the AngioJet Catheter and its predicate device exhibited comparable lengths (105 cm for AngioJet, 72 cm for the predicate), diameters (0.065" for each), kink radii (0.25 cm for AngioJet, 0.43 cm for the predicate), stiffness (0.56 lbs for AngioJet, 0.40 lbs for the predicate), and bond strength (3.89 ± 1.1 lbs for AngioJet, 6.13 ± 0.18 lbs for the predicate). The AngioJet Catheter is used over a guidewire, the predicate over a stylet. The materials are similar (PEBAX and stainless steel for AngioJet; polyester, latex, and stainless steel for the predicate). The AngioJet Catheter has a thin-walled (0.0055") dual lumen, while the predicate has a thicker walled single lumen (0.016").

To qualify its design, the Catheter underwent various in vitro functional tests such as flow rate, stagnation pressure, evacuation rate, leak and bond testing, thrombus removal, particulate generation, and hemolysis. All demonstrated adequate performance to design criteria, but because of the different mode of action, these tests were not duplicated with the predicate device.

Testing of AngioJet Catheters and the predicate device were conducted in animal arteries and veins. The AngioJet Catheter caused a subclinical rise in plasma hemoglobin, and a drop in hematocrit. Gross, histological, and SEM examination of treated vessels demonstrated that neither device causes serious injury to the vessel wall. Endothelial cell removal was greater with the predicate device than with the AngioJet Catheter. Biocompatibility testing of the AngioJet

Catheter included testing for cytotoxicity, hemolysis, systemic, intracutaneous and subchronic toxicity, mutagenicity, dermal sensitization, foreign body response, pyrogenicity, and skin irritation all per the Tripartite Biocompatibilty Guidance Document for blood contact devices. All results were negative. Sterilization validation was performed per AAMI National Standards and Recommended Practices for Ethylene Oxide Sterilization of Medical Devices (4th ed., 1992). Pyrogen testing was performed on sterilized, packaged devices per the Guideline for Validation of the Lumulas Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices, as proposed by CDRH. All these tests were passed. Because all these tests were performed as prescribed by existing standards, they were not duplicated on the predicate device, as it was assumed that the results would be similar.

As summarized above, where direct comparisons are meaningful, the results of the non-clinical tests performed support a determination that the AngioJet System is substantially equivalent to its predicate device.

8. Discussion of Clinical Tests

A two-phased clinical evaluation of the AngioJet System was conducted. Phase 1 was an uncontrolled feasibility study of the device in thrombosed leg conduits and A-V access grafts. Twenty-six AngioJet treatments were performed on 21 patients at three study sites. The study recorded 16 (62%) treatment successes, four (15%) partial successes, and six (23%) treatment failures. Six of the 21 patients were complication-free; the remaining 15 reported 41 complications. Only two of these were reported as being device related: one thromboembolism and one pseudoaneurysm, both without sequelae. Two patients died, for reasons not associated with the study.

The second phase of the study directly compared AngioJet to Fogarty-type thrombectomy catheters in a 1:1 randomization in patients with thrombosed A-V access grafts or leg conduits. The primary endpoint was restoration of dialysis through the treated graft (for A-V access grafts) or improvement in ABI or SVS/ISCVS score (for leg conduits) within 72 hours of treatment. The randomized treatment was scored a success if the endpoint was achieved without major complications (i.e., death, MI, stroke, or emergent surgery) and without use of another treatment for thrombus. A partial success was scored if another treatment for thrombus was used subsequently, but only if an angiogram performed immediately after study-assigned treatment confirmed some thrombus reduction by that treatment alone.
A total of 136 patients underwent 137 study-assigned treatment; 75 treatments were with AngioJet, and 62 were with Fogarty-type thrombectomy catheters. Of the total treatments, 118 were A-V access grafts; 19 were leg conduits. The table below displays treatment outcomes.

	Success	Partial Success	Failure	Not Scorable
AngioJet	48	7	15	5
Control	49	2	10	1

Defining a successful outcome as (success + partial success) / (success + partial success + failure), AngioJet achieved a successful outcome in 79% of the cases; the control did so in 84% (two-sided p-value = 0.510, by Fisher's Exact Test).

There were four AngioJet and five control deaths, none related to the study treatment. Six AngioJet patients reported seven complications related to the device: three mechanical failures, two extravasations, one rethrombosis, and one leg ischemia. Two control patients reported six complications related to the device: one bleeding (twice); the other bleeding, extravasation, hematoma, and perforation. All these events were without sequelae. Overall, of the 74 AngioJet patients, 60 (81%) reported one or more complications; of the 62 control patients, 42 (68%) reported one or more complications.

In addition, eight of the active study sites used AngioJet to treat a total of 25 other patients who were in emergency, off-protocol situations. Ten of these were for various venous thromboses, four for pulmonary thrombus, six for arterial thrombus beyond the protocol inclusion criteria (e.g., arteries which arise proximal to the aorto-iliac bifurcation), and five for patients who fit the inclusion criteria but not the exclusion criteria. All treatments were safely performed, and all achieved demonstrable thrombus reduction.

Of the 75 AngioJet treatments performed in this study, 66 were performed with the F105 Catheter model; nine were performed with the LF140 Catheter model. However, the LF140 Catheter is also the sole subject of a study of the AngioJet System in coronary applications. In the completed feasibility study, 90 patients (91 lesions) were evaluated after receiving thrombectomy treatment with the LF140 AngioJet Catheter in native coronary vessels and saphenous vein bypass grafts. Of these, 72 (79%) achieved the primary endpoint of acute success. There were four early and five late deaths, four Q-wave MIs, and one CVA. None of these complications were related to AngioJet treatment.

Finally, a trial conducted at four German sites treated 49 patients, of which 47 were treatment of leg conduits. The great majority of thrombus burden was removed by AngioJet treatment alone in 47 (96%) of the patients. Of the 47 leg patients, 38 (81%) had improved SVS/ISCVS score after AngioJet treatment; average ABI improved from 0.37 to 0.81, and average walking distance improved from 79 to 311 m after treatment.

In summary, the foregoing clinical results support the conclusion that the AngioJet system is substantially equivalent to the predicate device in the treatment of thrombosed A-V access grafts.