Traditional 510(k) Summary

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Date Summary Prepared: December 5, 2018

Device Trade Name: JETi 88 Peripheral Thrombectomy System

Common Name: Embolectomy/Thrombectomy Catheter

Classification Name: Embolectomy Catheter (21 CFR 870.5150)

Product Code: QEZ, Aspiration Thrombectomy Catheter

Predicate Device: ClearLumen II Peripheral Thrombectomy System (510(k) K172000)

Device Description:

The JETi 88 Peripheral Thrombectomy System consists of one aspiration catheter, which is connected to the JETi 88 Pump Set, one JETi 88 Peripheral Saline Drive Unit (SDU), and an Accessory Cart. A Sterile Accessory Kit and Non-Sterile Accessory Device are supplied. In use, thrombus enters the distal catheter tip via the suction force provided by the vacuum pump. The peripheral SDU and pump set deliver a stream of sterile saline through the secondary lumen to break up and dilute the thrombus within the catheter. The diluted thrombus and saline are drawn back through the primary lumen and deposited into the vacuum pump receptacle. No saline is injected into the patient during normal operation. The peripheral SDU, an adjustable mounting arm, a mounting bracket for vacuum canisters, an IV pole and a vacuum pump are contained on an accessory cart.

The peripheral catheter is a multi-lumen device that allows for simultaneous hydro-mechanical thrombus disruption and thrombus aspiration. It is designed to simultaneously deliver a stream of saline via a displacement pump within the distal tip of the catheter, while aspirating thrombotic material macerated by the saline stream.

The peripheral catheter has the ability to infuse fluid through the aspiration lumen and saline lumen.

For infusion through the aspiration lumen, an appropriate sized syringe filled with fluid is infused to the treatment area by passing through the side arm of the rotating hemostasis valve (RHV) that is attached to the catheter.

For infusion through the saline lumen, a clamp is used on the suction tubing to cut off vacuum.

The proximal end of the pump set consists of a spike and an in-line drip chamber that is used to pierce the saline bag and connect the pump set to the saline source. The cassette contains a piston pump and is mounted onto the peripheral SDU. The cassette is powered by the motor contained in the peripheral SDU. The distal end of the pump set has a connector, which mounts to the proximal end of the multi-port Luer adapter of the peripheral catheter and delivers the saline to the peripheral catheter.

The peripheral SDU is a reusable device. The fork drive of the peripheral SDU is designed to run the piston pump contained in the pump set to deliver the stream of saline to the peripheral catheter, when activated by the foot pedal. Vacuum is achieved with a vacuum pump, turned on/off with the pinch valve on the side of the SDU, which is also controlled by the foot pedal. The vacuum sensor is connected to the vacuum tubing, which is connected to the multi-port connector of the peripheral catheter. The peripheral SDU contains a microprocessor controlled circuit and firmware that monitors various functions of the motor and vacuum to assure that the device is functioning as expected. Various colored LED lights on the front panel indicate to the user what the current status is of the SDU. Energy is provided by a 24 volt external power supply, which is connected to mains power.

Indications for Use:
The JETi 88 Peripheral Thrombectomy System is intended to:

- remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, and

- subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.

Statement of Equivalence:
The subject device and the predicate share the same intended use and have similar technological characteristics.

Key differences between the subject and predicate devices are reflected in the following table.

Design Features	Predicate ClearLumen II Peripheral Thrombectomy System	Subject JETi 88 Peripheral Thrombectomy System
Catheter		
Catheter working length (cm)	115	100
Catheter connections and location	Two port "Y" connector with Luer connections on the proximal end of the catheter	Multi-port Luer adapter on the proximal end of the catheter
Pump Set		
Saline input tube length (feet)	4	6
Saline Drive Unit		
IEC 60601-1-2 edition complied with	3rd	4th
On/off control	Stopcock activated (vacuum sensing)	Foot pedal
Method to stop flow	Stop cock	Pinch valve
Pinch valve control	None	Mode button
Aspiration method	Single use, rechargeable 60 mL syringe (e.g., VacLock)	Vacuum pump
Location	Pole mounted outside sterile field	Mounted on cart outside sterile field
Vacuum sensor connector	Merit Medical custom plug	Standard RJ45
Accessory Cart	Not present	Present
Sterile Accessory Kit	Not present	Present
Non-Sterile Accessory Device	Not present	Present

The JETi 88 Peripheral Thrombectomy System is substantially equivalent to the predicate device.

Summary of Non-Clinical Performance Data:
Device evaluation consisted of *in vitro* testing performed pursuant to Walk Vascular's risk analysis. All data met the acceptance criteria and fell within pre-determined product specifications and external standard requirements. The following testing was performed to support the determination of substantial equivalence:

Design Verification Testing:

Pull test of welded and glued joints
Leak testing
Pressure testing
Flow testing
Kink testing
Embolic analysis
Saline stream containment
60601-1 Product and electrical safety testing

Biocompatibility Testing:
Biocompatibility testing was not conducted, as the test results from the ClearLumen II Thrombectomy System were adopted for the JETi 88 Peripheral Thrombectomy System.

Sterilization Testing:
Sterilization testing was not conducted, as the test results from the ClearLumen II Thrombectomy System were adopted for the JETi 88 Peripheral Thrombectomy System.

Transportation and Shelf Life Testing:
Transportation and shelf life testing was not conducted, as the test results from the ClearLumen II Thrombectomy System were adopted for the JETi 88 Peripheral Thrombectomy System.

The data from the *in vitro* testing above supports the substantial equivalence of the subject device to the predicate and reference device.

Summary of Pre-Clinical and Clinical Data:
No pre-clinical or clinical data were generated to establish substantial equivalence. Bench data are considered adequate to support a determination of substantial equivalence.

Summary:
Based on the intended use, and *in vitro* performance information provided in this premarket notification, the JETi 88 Peripheral Thrombectomy System is substantially equivalent to the predicate device.