October 5, 2018

Avenu Medical, Inc.
Ms. Rebecca Pine
Regulatory Consultant
27123 Calle Arroyo, Suite 2101
San Juan Capistrano, CA 92675

Re: K181725
Trade/Device Name: Ellipsys Vascular Access System (Ellipsys System), (Power Controller Model No. AMI-1001 & Catheter & Needle Model No. AMI-6005)
Regulation Number: 21 CFR 870.1252
Regulation Name: Percutaneous Catheter for Creation of an Arteriovenous Fistula for Hemodialysis Access
Regulatory Class: Class II
Product Code: PQK
Dated: September 4, 2018
Received: September 6, 2018

Dear Ms. Pine:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brian D. Pullin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181725

Device Name
Ellipsys Vascular Access System (Ellipsys System)
(Power Controller Model No. AMI-1001 & Catheter & Needle Model No. AMI-6005)

Indications for Use *(Describe)*
The Ellipsys System is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER

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Contact Person: Dave Campbell
Date Prepared: August 28, 2018

II. DEVICE

Name of Device: Ellipsys Vascular Access System (Ellipsys® System), Model AMI-1001, Model AMI-6005
Common or Usual Name: Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access
Regulatory Class: II
Product Code: PQK
Regulation Number: 21 CFR 870.1252

III. PREDICATE DEVICE

Name of Device: Ellipsys Vascular Access System (Ellipsys® System), Model AMI-1000, Model AMI-6050
De Novo Classification Number: DEN170004
Regulation Number: 21 CFR 870.1252

This predicate has not been subject to a recall.

IV. DEVICE DESCRIPTION

The device that is the subject of this 510(k) is a modified Ellipsys Vascular Access System. The Ellipsys System recently gained market clearance through the *de novo* classification pathway (DEN170004). The specific modifications subject to this submission consist of a redesigned Ellipsys Power Controller (AMI-1001) and several minor modifications to the Ellipsys catheter and crossing needle (AMI-6005). The catheter and crossing needle are supplied sterile (EtO).

The modified Ellipsys System remains a catheter-based system that is used to percutaneously create a vascular anastomosis of the proximal radial artery and adjacent vein using direct current (DC) thermal heating. The Ellipsys Power Controller (AMI-1001) is software driven and guides the user through the procedure using visual prompts via an LCD display. The

Controller monitors the closure of the catheter tip, and supplies controlled DC energy to the catheter's heating element. The Ellipsys Catheter and Crossing Needle (AMI-6005) are a sterile single-use disposable devices that are responsible for approximating (bringing together) the arterial and venous vessel walls and applying thermal energy to create an anastomosis and join the two target vessels. The catheter is designed to be compatible with .014" guidewires and 6 French introducer sheaths commonly used with vascular interventional procedures. The system is designed to be used in a surgical or radiological suite or office based procedure room.

V. INDICATIONS FOR USE

The Ellipsys® System is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Ellipsys Vascular Access System described and cleared by FDA in *de novo* DEN170004, serves as the predicate for the modified device that is the subject of this 510(k). Endovascular creation of an AV fistula is the technological principle for both the modified Ellipsys System and the predicate device. Both systems utilize ultrasonically guided endovascular techniques and instrumentation for approximating (bringing together) the arterial and venous vessel walls and applying DC thermal energy to join the target vessels creating a side by side anastomosis and thereby creating an AV fistula for dialysis access.

The modified and predicate devices are based on the same technological elements as described below:

Power Controller, Model #AMI-1001

- Software controlled device that guides the user through the procedure using visual prompts via a graphical user interface, monitors the closure of the catheter tip, and supplies controlled DC energy to the catheter's heating element.
- Software provides closed loop control of the sealing algorithm and thermal profile.
- Both devices utilize the same sealing algorithm and thermal profile.

Vascular Access Kit, Model # AMI-6005 (Catheter & Crossing Needle)

- The Crossing Needle is inserted into the vasculature over a guidewire through an introducer sheath to cross from the vein into the adjacent artery.
- The Catheter is inserted over the guidewire through the introducer sheath so the distal tip is inside the artery and the proximal portion of the tip remains in the vein. The catheter mechanically captures and approximates the vessel walls.
- The Catheter seals the walls of the proximal radial artery and the adjacent vein creating an arteriovenous fistula utilizing DC thermal energy delivered by the Power

Controller.

The following provides a technological comparison between the modified and predicate devices:

The modified Power Controller (AMI-1001) is a redesign of the predicate using updated hardware and software to improve manufacturability and availability. Although the hardware and software design has changed, the same control algorithm and thermal profile were retained in the new design.

The modified Vascular Access Kit contains the Crossing Needle and Catheter. There are no changes to the crossing needle as it is identical to the predicate. There are no changes to the basic design, patient contact materials, or function of the modified Catheter aside from minor enhancements.

A comparison of the characteristics of the modified Ellipsys System versus the predicate is provided in **TABLE 6.1** below. (Note: The differences between the Modified Ellipsys System and the predicate are highlighted in blue font)

TABLE 6.1 - Device Comparison

Characteristic	**Modified Device (AMI-1001/AMI-6005)**	**Predicate Device (AMI-1000/AMI-6050)**	**Comparison**
Indication for Use	The Ellipsys System is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis	The Ellipsys System is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis	Identical
Power Controller			
Enclosure	Molded Plastic	Sheet Metal	Similar
Energy Source & Type	DC thermal energy (Same)	DC thermal energy	Identical
User Interface	LCD Display / Multifunction Membrane Switch	Tablet PC w/Touch Screen	Similar
Main Board and Processor	MCU Board (PCBA) w/ ST Micro 32 bit processor	MCU Board (PCBA) w/ Freescale 32 bit processor	Similar
System Software	System software (C^{++} code) (Same)	System software (C^{++} code)	Similar
GUI software	Linux OS	Windows OS	Similar
Temperature Control Algorithm	PID control (Same)	PID control	Identical

Temperature Profile	Maximum of 7 cycles (2 sec @ 700°F followed by 8 sec cooling phase) (Same)	Maximum of 7 cycles (2 sec @ 700°F followed by 8 sec cooling phase)	Identical
Catheter Compatibility	AMI-6005	AMI-6050	Similar
Crossing Needle			
Material/Design	ABS/Stainless Steel (Same)	ABS/Stainless Steel	Identical
Design	No change	Existing	Identical
Catheter			
Function & Operation	Function: Approximates (brings together) the target arterial and venous vessel walls and applies thermal energy to create an anastomosis. (Same) Operation: Catheter Handle & Thumb Tab control insertion and Actuation of the tip (Same)	Function: Approximates (brings together) the target arterial and venous vessel walls and applies thermal energy to create an anastomosis. Operation: Catheter Handle & Thumb Tab control insertion and Actuation of the tip.	Identical
Materials - Patient Contact	ABS/Polyimide/Parylene/SS (Same)	ABS/Polyimide/Parylene/SS	Identical
Catheter Design	Minor enhancements	Existing	Similar

The minor technological differences between the modified Ellipsys System and the predicate device do not raise different questions of safety and effectiveness and the performance data described in Section VII establishes that the modified device is substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the special controls requirements of 21 CFR 870.1252 and the substantial equivalence determination. All devices used for evaluation performance were representative of finished devices.

1) Clinical Performance Testing

Clinical data was not performed in support of the special controls requirement and substantial equivalence for the following reasons:

1) The modified Power Controller utilizes the same control algorithm, energy type and source, and heat profile as the predicate.
2) The design and function of the modified catheter remain essentially unchanged from the predicate.

2) Animal Testing

An acute animal study was conducted in the sheep model to demonstrate that the modified device performs as intended under anticipated conditions of use. The following characteristics were addressed by the study:

i. Delivery, deployment, and retrieval of the device;
ii. Compatibility with other devices labeled for use with the device;
iii. Patency of the fistula;
iv. Characterization of blood flow at the time of the fistula creation procedure; and
v. Gross pathology and histopathology assessing vascular injury and downstream embolization.

Chronic follow-up was not performed as the study demonstrated the equivalence of fistulae created by the modified device in a side by side comparison with the predicate. Patency, blood flow, gross pathology and histopathology were demonstrated to be equivalent. Therefore, chronic performance is expected to be the same as the predicate.

This study demonstrated that the Ellipsys Vascular Access System, Model AMI-1001, Model AMI-6005 can safely create a percutaneous AV fistula equivalent in performance to that which is created by the predicate device.

3) Non-Clinical Performance Testing

All necessary non-clinical performance testing was performed for the modified Ellipsys Vascular Access System to demonstrate that the modified device performs as intended under anticipated conditions of use. The following characteristics were addressed by the testing:

i. Simulated-use testing in a clinically relevant bench anatomic model to assess the delivery, deployment, activation, and retrieval of the device;
ii. Tensile strengths of joints and components;
iii. Accurate positioning and alignment of the device to achieve fistula creation; and
iv. Characterization and verification of all dimensions.

The non-clinical performance testing demonstrated that the physical characteristics of the modified device performed as expected meeting all required specificaitons.

4) Electromagnetic Compatibility (EMC) and Electrical Safety Testing

Electromagnetic Compatibility (EMC) and Electrical Safety testing were conducted on the modified Ellipsys Vascular Access System, AMI-1001 and AMI-6005. The system complies with the IEC 60601-1/A1:2012 standard for electrical safety and IEC 60601-1- 2:2007 standard for EMC.

5) Software Verification and Validation Testing

Software verification, validation and hazard analysis was completed to demonstrate the minor design enhancements and has no adverse effect on the established performance of the device.

6) Biocompatibility of Patient-Contacting Components

No new patient-contacting components are incorporated into the device, therefore, the biocompatibility testing for the predicate has been adopted in support of the required biocompatibility special control.

7) Sterilization Performance

The construction, packaging and density of the modified product is identical to the predicate therefore the existing EO sterilization process was adopted in support of the special control for sterility.

8) Shelf Life Performance

The construction, packaging and density of the modified product is identical to the predicate therefore the existing package shelf life validation demonstrates continued sterility, package integrity, and device functionality over the identified shelf life.

9) Device Labeling

Labeling for the device includes the following characteristics as is supplied as part of this application.

i. Instructions for use;;
ii. Identification of system components and compatible devices;;
iii. Expertise needed for the safe use of the device;
iv. A detailed summary of the clinical testing conducted and the patient population studied; and
v. A shelf life and storage conditions.

As a prescription device the modified Ellipsys System complies with 21 CFR 801.109

VIII. CONCLUSIONS

Based on a comparison of the intended use and an assessment of the different technological characteristics related to the modifications, it has been established that the modified Ellipsys System is substantially equivalent to the legally marketed predicate device. Minor differences in technological characteristics did not raise new or different questions of safety and effectiveness. Additionally, the data and information in the 510(k) demonstrate that the modified device is substantially equivalent to the predicate device.