January 25, 2019

Avenu Medical, Inc.
Dave Campbell
VP of Quality Assurance & Regulatory Affairs
27123 Calle Arroyo, Suite 2101
San Juan Capistrano, California 92675

Re: K183615
Trade/Device Name: Ellipsys Vascular Access System (Ellipsys System), (Power Controller Model No. AMI-1001, Catheter Model No. AMI-6005, and Crossing Needle Model No. AMI-3000)
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: December 19, 2018
Received: December 26, 2018

Dear Dave Campbell:

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)*
K183615

Device Name
The Ellipsys Vascular Access System (Ellipsys System)
(Power Controller, Model No. AMI-1001; Catheter, Model No. AMI-6005, & Crossing Needle, Model No. AMI-3000)

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 2.0 mm and less than 1.5 mm 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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Summary

I. SUBMITTER

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Phone: 949-878-0886
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Contact Person: Dave Campbell
Date Prepared: January 21, 2019

II. DEVICE

Name of Device: Ellipsys Vascular Access System (Ellipsys® System), Model AMI-1001, Model AMI-6005 and AMI-3000
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-1001, Model AMI-6005
510(k) Number: K181725
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 510(k) pathway (K181725). This submission describes the modification to the Ellipsys Vascular Access Kit (AMI-6005) only, which consists of the Ellipsys Crossing Needle and Catheter. Specifically, the Crossing Needle and Catheter are being separated and individually packaged using the same packaging materials and processes. 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 Crossing Needle (AMI-3000) and Ellipsys Catheter (AMI-6005) are 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. Both the crossing needle and catheter are 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 510(k) K181725, serves as the predicate for the modified device that is the subject of this 510(k). Both the modified device and the predicate device are identical in design and intended use. The technological principle for both the modified Ellipsys System and the predicate device is endovascular creation of an AV fistula. 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.

Ellipsys Catheter, Model # AMI-6005

- 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.

Ellipsys Crossing Needle, Model # AMI-3000

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

The Power Controller (AMI-1001) remains unchanged from the predicate. No changes have been made to the hardware, software, power source, control algorithm or thermal profile.

The Vascular Access Kit containing the Crossing Needle and Catheter has been modified to separate the Crossing Needle and Catheter and provide each device in individual sterile packages. The labeling will change to reflect the new model number for the Crossing Needle. There are no other changes to the Crossing Needle or Catheter and both are identical to the predicate. There are no changes to the basic design, patient contact materials, packaging materials or function of the modified Crossing Needle and Catheter aside from separating them into individual packages.

A comparison of the characteristics of the modified Ellipsys System versus the predicate is provided in **TABLE 6.1** below.

TABLE 6.1 - Device Comparison

Characteristic	**Modified Device (AMI-1001/AMI-6005/AMI-3000)**	**Predicate Device (AMI-1000/AMI-6050)**	**Comparison**
Indication for Use	No change	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			
Design: Hardware/Electronics	No change	Existing	Identical
Energy Source & Type	No change	DC thermal energy	Identical
System Software	No change	System software (C^{++} code)	Identical
Temperature Control Algorithm	No change	PID control	Identical
Temperature Profile	No change	Maximum of 7 cycles (2 sec @ 700°F followed by 8 sec cooling phase)	Identical
Catheter Compatibility	No change	AMI-6005	Identical
Crossing Needle			
Design	No change	Existing	Identical
Materials - Patient Contact	No change	ABS/Stainless Steel (SS)	Identical

Packaging Configuration	Crossing Needle individually packaged in a separate Tyvek pouch w/ backer card	Crossing Needle & Catheter packaged together in a Tyvek pouch w/ backer card	Similar
Catheter			
Function & Operation	No change	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	No change	ABS/Polyimide/Parylene/SS	Identical
Catheter Design	No change	Existing	Identical
Packaging Configuration	Catheter individually packaged in a separate Tyvek Pouch w/ backer card	Crossing Needle & Catheter packaged together in a Tyvek Pouch w/ backer card	Similar

The minor packaging configuration difference between the modified Ellipsys System and the predicate device does 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.

1) **Clinical Performance Testing**

   Clinical data is not required in support of the special controls requirement and substantial equivalence since the intended use, technological characteristics, design and function of the Power Controller, Crossing Needle, and Catheter remain unchanged from the predicate.

2) **Animal Testing**

   The intended use, technological characteristics, design, function, and manufacturing processes of the Power Controller, Crossing Needle, and Catheter remain unchanged from the predicate. Therefore, the animal test data from the predicate has been adopted in support of the special controls requirement and substantial equivalence.

3) **Non-Clinical Performance Testing**

   The technological characteristics, design, function and the manufacturing processes of the Power Controller, Crossing Needle and Catheter remain unchanged from the predicate. Therefore, the previously validated non-clinical performance test data for the predicate has been adopted in support of the special control requirement and substantial equivalence.

4) Electromagnetic Compatibility (EMC) and Electrical Safety Testing

The technological characteristics, design, function and the manufacturing processes of the Power Controller, Crossing Needle and Catheter remain unchanged from the predicate. Therefore, the Electromagnetic Compatibility (EMC) and Electrical Safety test data from the predicate has been adopted in support of the special controls requirements and substantial equivalence.

5) Software Verification and Validation Testing

No new software was incorporated into the modified device; therefore, the software verification, validation and hazard analysis test data from the predicate has been adopted to support the software special control and substantial equivalence requirements.

6) Biocompatibility of Patient-Contacting Components

No new patient-contacting components are incorporated into the modified device; therefore, the biocompatibility test data from the predicate has been adopted to support the biocompatibility special control and substantial equivalence.

7) Sterilization Performance

The construction, packaging and configuration of the modified product was evaluated against the predicate and was determined to pose no additional challenge to the existing EO sterilization process (SAL 10^{-6}) and therefore has been adopted for the modified device in support of the special control for sterility and substantial equivalence.

8) Shelf Life Performance

The construction and packaging of the modified product is identical to the predicate and does not pose any additional challenge to the packaging system; therefore, the existing package shelf life validation has been adopted in support of the special control for shelf life performance and substantial equivalence.

9) Device Labeling

Labeling for the device includes the following characteristics and 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) Shelf life and storage conditions.

VIII. CONCLUSIONS

Based on a comparison of the intended use and an assessment of the technological characteristics related to the minor packaging configuration change, it has been established that the modified Ellipsys System is substantially equivalent to the legally marketed predicate device. The minor difference in the packaging configuration of the Crossing Needle and Catheter does not raise new or different questions of safety and effectiveness. Furthermore, the information provided in this 510(k) demonstrates that the modified device is substantially equivalent to the predicate device.