July 14, 2022

AVIA Vascular
℅ Jonathan Holmes
Senior Manager, Regulatory Affairs
MedVenture Health
299 S Main Street, Suite 2300
Salt Lake City, Utah 84111

Re: K220258
Trade/Device Name: 20G Open-System Ally Device Kit (AV100000), 22G Open-System Ally Device Kit (AV110000)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: June 14, 2022
Received: June 15, 2022

Dear Jonathan Holmes:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Wolloscheck, Ph.D.
For Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
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OHT3: Office of GastroRenal, ObGyn,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220258

Device Name
20G Open-System Ally Device Kit (AV100000);
22G Open-System Ally Device Kit (AV110000)

Indications for Use *(Describe)*
The Ally device is attached to a PIV catheter system for blood sampling into a vacuum tube or syringe.

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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AVIA VASCULAR
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K220258
510(k) SUMMARY

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DATE PREPARED: July 14, 2022

SUBJECT DEVICE:

Trade Name:	20G Open-System Ally Device Kit (AV100000); 22G Open-System Ally Device Kit (AV110000)
Common Name:	Blood Collection Tubes, Vials, Systems, Serum Separators
Regulation Name:	Blood Specimen Collection Device
Classification Panel:	Clinical Chemistry
Regulatory Class:	Class II
Product Code:	JKA
Regulation Number:	21 CFR 862.1675

PREDICATE DEVICE:

Proprietary Name:	PIVO™
Common Name:	Blood Collection Tubes, Vials, Systems, Serum Separators
Regulation Name:	Blood Specimen Collection Device

510(k) Number: K190604

PRODUCT DESCRIPTION:

The Ally device by Avia Vascular is intended to be attached to a peripheral intravenous (PIV) catheter system for use as a needleless blood draw device into a vacuum tube or syringe. Once attached to a PIV catheter system, the Ally device functions by extending a conduit tube through the internal lumen of the PIV catheter so that the distal tip of the Ally conduit extends beyond the tip of the PIV catheter, allowing for sampling of blood. The Ally device is a sterile, single use device.

INTENDED USE/INDICATION FOR USE:

Intended Use: Venous blood drawing.

Indications for Use: The Ally device is attached to a PIV catheter system for blood sampling into a vacuum tube or syringe.

TECHNOLOGICAL COMPARISION TO PREDICATE DEVICE:

Characteristic	Ally Blood Collection Device (K220258) (Subject Device)	PIVO™ (K190604) (Predicate Device)	Analysis of Differences
Indications for Use	The Ally device is attached to a PIV catheter system for blood sampling into a vacuum tube or syringe.	The PIVO™ device attaches to a peripheral IV catheter system for use as a direct blood draw device into a vacuum tube or a syringe.	Substantially Equivalent The indication for use is the same. The difference in phrasing does not alter the meaning of the indication for use or negatively impact the clarity.
Device Configurations and Colors	• 20G – Pink • 22G – Blue	• 20G – Pink • 22G – Blue • 24G – Yellow	Substantially Equivalent The subject device utilizes the same primary color as the predicate for equivalent gauge sizes.
Distal Tube Material	Polyimide	Polyimide	Same

Characteristic	Ally Blood Collection Device (K220258) (Subject Device)	PIVO™ (K190604) (Predicate Device)	Analysis of Differences
Proximal Tube Material	Polyurethane	Pebax	Different Performance and biocompatibility testing pertaining to the proximal tubing (leak, tensile, hemolysis) show the component to be equivalent to the predicate with respect to applicable requirements. The subject devices were determined to be biocompatible for their intended use per ISO 10993-1 testing as noted in the summary below. Material difference does not raise new questions for safety or effectiveness with respect to the intended use.
Inner Tubing Length	• 20G and 22G Open-System – 6.253”	• 20G – 5.85” • 22G – 5.85” • 24G – 141.2mm	Different Distal tube lengths of the subject device are designed such that the tubing can be extended throughout a PIV catheter system in the same manner as the predicate. Appropriateness was demonstrated through testing (dimensional, hemolysis, flow testing, usability). Differences in length do not raise new questions for safety

Characteristic	Ally Blood Collection Device (K220258) (Subject Device)	PIVO™ (K190604) (Predicate Device)	Analysis of Differences
			or effectiveness with respect to the intended use.
Outer Diameter (OD) of Distal Inner Tubing	• 20G Open-System – 0.0270” • 22G Open-System – 0.0210”	• 20G = 0.709mm max • 22G = 0.543mm max • 24G = 0.400mm max	Same
Packaging	Tyvek Pouch	Tyvek Pouch	Same
Sterilization	Ethylene Oxide	Gamma	Different The method of sterilization for the subject device was found to be valid for a sterility claim and appropriate through packaging, biocompatibility, and sterilization evaluations. Both subject device and predicate devices are classified as sterile.

PERFORMANCE TESTING

The Ally Blood Collection Device was thoroughly tested and verifies that it performs as designed and is suitable for its intended use.

Performance Testing included the following:

- Flow Conduit Inner Diameter
- Flow Conduit Outer Diameter
- Flow Conduit Effective Length and Flow Conduit Exposure Length
- Open-System Introducer Length
- Extension Tubing Inner Diameter
- Flow Conduit-to-Extension Tubing Assembly Tensile
- Extension Leg-to-Stop Ring Assembly Tensile
- Extension Tubing-to-Proximal Luer Assembly Tensile
- Guide Cannula-to-Introducer Assembly Tensile
- Introducer to Housing Retention

- Sheathing Cannula Tensile Testing
- Kink Diameter
- Aspiration Flow Rate
- Leak Decay
- Housing Seal Leak Decay Testing
- Particulate testing per USP <788>

Biocompatibility per ISO 10993-1 for an external communicating device, limited (<24 hour) blood contacting device.

- Cytotoxicity – MEM Elution – ISO 10993-5
- Sensitization – ISO 10993-10
- Irritation – ISO 10993-10
- Material Mediated Pyrogenicity – ISO 10993-11
- Acute Systemic Toxicity – ISO 10993-11
- Hemolysis (direct and indirect) – ISO 10993-4
- Mechanically Induced Hemolysis – ASTM F-756-17
- Complement Activation Assay – C3a and SC5b9 Methods– ISO 10993-4
- Partial Thromboplastin Time (PTT) – ISO 10993-4
- Platelet and Leucocyte Count (PLC) – ISO 10993-4

The subject Ally device met all predetermined acceptance criteria and raised no new concerns regarding safety or effectiveness.

CONCLUSION:

The subject Ally has been demonstrated to be substantially equivalent in design, materials, sterilization, principles of operation, performance, and indications for use to the predicate PIVO™ device (K190604). Any differences do not raise new or different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.