August 19, 2022

Advcare Medical
Meng Tan
CEO
No. 36, Sinsing Street, Shulin District
New Taipei, 23877
Taiwan

Re: K212525
Trade/Device Name: Advcare Vial Direct to Bag (VDB) Needle-free Admixture Devices
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: August 5, 2021
Received: August 11, 2021

Dear Meng Tan:

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,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K212525

Device Name
Advcare Vial Direct to Bag (VDB) Needle-Free Admixture Devices

Indications for Use *(Describe)*
Advcare Vial Direct to Bag (VDB) Needle-free Admixture devices are intended for drug reconstitution and transfer of fluids from drug vials into the IV bag containing infusion solution and attaching an IV set to administer infusion liquid to patient. The devices are provided as single-use, sterile, and non-pyrogenic products. The VDB-13 & 20 has an integrated vial adaptor that is used to reconstitute and admix drugs from a drug vial into the solution IV bag. The devices are intended for use in healthcare environments by clinically trained healthcare professional providers to aid and support prescribed treatment and therapy.

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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K212525 510(k) Summary

Submitter:	Advcare Medical No. 36 Sinsing Street Shulin District, New Taipei City, 23877
Application Correspondent:	Meng T. Tan
Telephone Number:	+886-2-3501-7479
Fax Number:	+886-2-8970-1448
E-mail:	sales@advcaremed.com
Date Prepared:	August 17, 2022
Trade Name:	Advcare Direct to Bag (VDB) Needle-free Admixture Devices
Common or Usual Name:	I.V. Fluid Transfer Set
Regulation Medical Specialty:	General Hospital
Regulation Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Product Code:	LHI
Device Class:	2
Predicate Device:	K201415 Vial2Bag-Advanced

Device Indications For Use:

Advcare Vial Direct to Bag (VDB) Needle-free Admixture devices are intended for drug reconstitution and transfer of fluids from drug vials into the IV bag containing infusion solution and attaching an IV set to administer infusion liquid to patient. The devices are provided as single-use, sterile, and non-pyrogenic products. The VDB-13 & 20 has an integrated vial adaptor that is used to reconstitute and admix drugs from a drug vial into the solution IV bag. The devices are intended for use in healthcare environments by clinically trained healthcare professional providers to aid and support prescribed treatment and therapy.

Device Description:

Advcare IV fluid transfer Vial Direct to Bag (VDB) VDB-13 & 20 Needle-free Admixture Devices are designed for drug reconstitution and transfer of fluids from drug vials into IV bag containing infusion solution. The VDB-13 & 20 serve as a fluid pathway for standard IV set to administer fluid to patient while minimizing exposure to drug aerosols and spills. The VDB-13 & 20 has an integrated vial adaptor that is used to reconstitute and admix drugs from a drug vial into the solution IV bag.

Both IV fluid transfer system designs consist of a body, piercing spike, spike cover, IV port, and twist-off for the IV administration set. The VDB 13mm and 20mm has an integrated Vial Adaptor for access to the drug/solution vial. Both system transfer drug into an IV bag and to an external IV administration set to administer fluid to patient. The products do not contain any medicinal substances, and can be used with standard drug vials. It is intended for use in healthcare facilities by care-giver to aid and support prescribed treatment and therapy.

Technological Characteristics and Substantial Equivalence:

A technological comparison table is provided below that compares the subject devices and predicate device.

	Predicate K201415	Advcare VDB 13 & 20	Equivalence to Predicate
Intended use	The Vial2Bag Advanced intended use is to allow the administration of a fluid from an IV container to a patient's vascular system through a needle or catheter inserted into a vein. The Vial2bag-Advanced has 20mm vial adaptor to access infusion system.	Advcare IV fluid transfer Vial Direct to Bag (VDB) 13 & 20 intended use is to allow the administration of a fluid from an IV container to a patient's vascular system through a needle or catheter inserted into a vein. The Advcare IV fluid transfer Vial Direct to Bag (VDB) Devices has 13mm and 20mm vial adaptor to access infusion system.	Comment 1
Target users	Pharmacist or other healthcare professionals	Pharmacist or other healthcare professionals	Same
Use Environment	Hospital, Clinics	Hospital, Clinics	Same

Interaction with other devices	For all uses, device will connect to an IV solution container and a primary administration set. Based on IFU.	For all uses, device will connect to an IV solution container and a primary administration set. Based on IFU	Same
Vial size	20mm	20mm and 13 mm	Comment 1
IV bag sizes	50ml,100m, 250ml	All standard IV bags	Comment 2
Sterilization	Eto	Eto	Same
Prescription use	Rx only	Rx only	Same
Piercing Spike	Plastic-Single Lumen	Plastic-Single Lumen	Same
Materials	Medical Grade Plastics	Medical Grade Plastics	Comment 3

Discussion of differences in technological characteristics:

Comment 1- Advcare IV fluid transfer Vial Direct to Bag (VDB) Devices has two designs, 13mm vial adaptor and 20mm vial adaptor designs. The predicate device only has a 20mm vial adaptor. The VDB-13 is to accommodate smaller drug vial sizes. Performance testing confirmed that the VDB- 13mm vial adaptor design does not raise different questions of safety and effectiveness. The materials, function, and principal of operation are very similar as the primary predicate 20mm vial adaptor.

Comment 2 - the predicate device is for use with 50ml, 100ml and 250ml IV solution bags. The Advcare IV fluid transfer Vial Direct to Bag (VDB) Devices are for use with all standard IV solution bags. Standard IV solution bags available on the market utilize a standard spike connector and this is consistent for all size standard solution bags. The Advcare IV fluid transfer Vial Direct to Bag (VDB) Devices utilize a standard bag spike that is compatible with all size standard IV solution bags and as such, will not raise any new safety or efficacy questions.

COMPARATIVE SAFETY AND PERFORMANCE: The Advcare fluid transfer Vial Direct to Bag (VDB) 13 & 20 uses the same technique and parameters as the predicate device for reconstituting and transferring medication. There are no differences in technology. Therefore, the technology used in the Advcare fluid transfer Vial Direct to Bag (VDB) 13 & 20 does not affect the comparative safety and performance of the device.

Comment 3- Biocompatibility testing demonstrated the materials are biocompatible.

PERFORMANCE DATA:

The following non-clinical data were provided in support of the substantial equivalence determination.

Performance Testing

Testing was conducted to validate that the Advcare IV fluid transfer Vial Direct to Bag (VDB) VDB-13 & 20 Needle-free Admixture Devices met the applicable design and performance requirements throughout its shelf life, conformity to applicable standards, and demonstrate substantial equivalent to the predicate device.

Conformity to Standard:

ISO 8536-4: 2019

Additional Performance Testing to internal specifications:

- Product Functionality According to IFU
- Cap Detachment Force
- Spike Penetration Force
- Air Leakage Test
- Vial Adaptor Tensile Detachment Force From Drug Vial
- Vial Adaptor Torsional Breakage Test
- Spike to IV Bag Port Tensile Detachment Force
- IV Admin Spike to VDB-IV Port Attachment Force
- Vial Attachment Force
- Vial Detachment Force
- Flange Breakage
- Flow Rate
- Coring of IV Bag Port
- Coring and Fragmentation of Vial Stopper
- Twist-Off Bonding To IV Spike
- Leakage After Removal of Twist OFF
- Leakage at VDB-IV Spike to IV Bag port following assembly of components
- Leakage at VDB-IV Port to IV Admin Spike following assembly of components
- Dimensional Measurements of the IV spike lumens
- Dimensional Measurements of the Vial Adaptor Retention Feature.
- Chemical Compatibility Testing.
- Dose Concentration Study
- Dose Accuracy (Transfer of vial contents to the IV bag & to the administration set)

Biocompatibility

Accordance to ISO 10993-1, the Advcare IV fluid transfer Vial Direct to Bag (VDB) VDB-13 & 20 Needle-free Admixture Devices are classified as an externally communicating device with prolonged contact duration (>24 hours to 30 days) and blood path indirect contact. The finished device's patient contacting parts were tested in accordance with the tests recommended in the FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk

management process." The following biocompatibility tests has been successfully conducted.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute System Toxicity
- Subacute System Toxicity
- Pyrogenicity
- Hemolysis
- Particulate Test
- Bacterial Endotoxin

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014. Sterilization of health-care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices. The sterilization method provides a sterility assurance level (SAL) of 10^{-6}.

CLINICAL DATA:

No clinical trial was performed

CONCLUSION:

In summary, the Advcare IV fluid transfer Vial Direct to Bag (VDB) VDB-13 & 20 Needle-free Admixture Devices subject of this Premarket Notification is considered to be substantially equivalent in its intended use, technological, material, and performance to the predicate device, Vial2bag: Advanced (K201415).