September 20, 2024

Ecomed Solutions, LLC
Christina Bloxton
Regulatory
214 Terrace Drive
Mundelein, Illinois 60060

Re: K234129
Trade/Device Name: Ecomed Disposable Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: August 21, 2024
Received: August 21, 2024

Dear Christina Bloxton:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234129

Device Name
Ecomed Disposable Administration Sets

Indications for Use *(Describe)*
Ecomed Disposable Administration sets are used to transfer fluids from a container to a patients vascular system through a needle or catheter inserted into the vein.

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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K234129.510K SUMMARY

Prepared on: 9-12-2024

CONTACT DETAILS

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Correspondent Contact Telephone: 262-220-3463

Correspondent Contact: Ms. Christina Bloxton

Correspondent Contact Email: christina.bloxton@ecomed-solutions.com

1.1 DEVICE NAME

Device Trade Name: Ecomed Disposable Administration Sets

Classification Name: Set, Administration, Intravascular

Regulation Number: 880.5440

Product Code(s): FPA

Device Class: Class II

1.2 LEGALLY MARKETED PREDICATE DEVICES

Predicate: K090012 , Disposable Infusion Set (WeiGao)

1.3 DEVICE DESCRIPTION SUMMARY

The Ecomed Disposable Administration Sets are a family of sterile, single use gravity sets composed of common components that are used to administer fluids.

Each set is comprised of a subset of common components which are broadly used throughout industry including roller clamp, slide clamp, a flow regulator, a drip chamber, an infusion line filter, fluid delivery tubing, Burette w/ needle-free injection site and vent/cap and drip chamber 60 drop,

injection site, connectors between parts of the set, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

This family of sets and components is broken down into the following main categories: Primary set, Tee set, Flow Controller Set, Filter Set, and Burette Set.

1.4 INTENDED USE/INDICATIONS FOR USE

Ecomed Disposable Administration sets are used to transfer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

1.5 INDICATIONS FOR USE COMPARISON

The indications for the proposed and predicate devices are the same.

1.6 TECHNOLOGICAL COMPARISON

Identification		**Proposed Device**	**Predicate Device, (Primary)**	**Explanation of Variation**
Name		**Ecomed Disposable Administration Sets**	**Disposable Infusion Set (WeiGao)**	
Regulatory Information	510(k)#	This submission	K090012	N/A
	Predicates	K090012	K060082	N/A
	Product Code	FPA	FPA	Same
	Subsequent product code	N/A	N/A	N/A
	Class	2	2	Same.
	Combination Product	No	No	Same
	Regulation Number	880.5440	880.5440	Same
	Regulation Generic Name	Intravascular administration set	Intravascular administration set	Same.
Intended use	Regulation Intended Use	An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.	An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.	Same.
	Indications	Ecomed Disposable Administration sets are used to transfer fluids from a container to a patients vascular system through a needle or catheter inserted into the vein.	Disposable Infusion set is used to transfer fluids from a container to a patients vascular system through a needle or catheter inserted into the vein.	Same.
	Intended (target) population	Adult and Pediatric	Adult and Pediatric	Same.

Identification		Proposed Device	Predicate Device, (Primary)	Explanation of Variation
Name		Ecomed Disposable Administration Sets	Disposable Infusion Set (WeiGao)	
	Intended user	Healthcare professional (doctor, nurse, technician)	Healthcare professional (doctor, nurse, technician)	Same.
	Environment of use	Professional Healthcare Facility, Transport (ambulatory) Environment	Professional Healthcare Facility, Transport (ambulatory) Environment	Same.
Technology	Anatomical sites	Peripheral Intravenous	Peripheral Intravenous	Same.
	Contact Type	External communicating device -blood path, indirect	External communicating device -blood path, indirect	Same.
	Contact duration	Prolonged 24hours < 30 days	Prolonged 24hours < 30 days	Same.
	Biocompatibility	ISO 10993-1	ISO 10993-1	Same.
	Storage conditions	General warehouse.	General warehouse.	Same.
	Shelf Life	2 years	2 years	Same. Shelf-life testing has confirmed the stability and equivalence of the proposed device.
	Performance	ISO 8536-4	ISO 8536-4	Same.
	Mode of fluid delivery	Gravity	Gravity	Same.
	Control mechanism	Roller Clamp ABS Slide Clamp PE Flow Regulator PE ISO 8536-4 ISO 8536-13 ISO 8536-14 ISO 10993-1	Flow Regulator ABS or PE ISO 8536-4 ISO 10993-1	Different. The subject device includes additional industry standard components included in the same consensus standard (ISO 8536-4) that the predicate devices are compliant to for other components. Both manual and graduated flow controllers are industry standard components included in the same consensus standard (ISO 8536-4) used for the same purpose. The difference does not raise any new issues of safety and effectivity. Since the predicate was cleared, the standard has been updated to split out the flow controller requirements in two separate new standards (ISO 8536-13 & ISO 8536-14) and the new components are compliant to the current revisions.
	Tubing (ID X OD)	3mm x 4mm 0.8mm x 2.4mm ISO 8536-4 ISO 10993-1	3mm X 4mm ISO 8536-4 ISO 10993-1	Different. The subject devices include 0.8mm x 2.4mm tubing size in addition to the standard 3mm x 4mm tubing in the predicate.

Identification		Proposed Device	Predicate Device, (Primary)	Explanation of Variation
Name		Ecomed Disposable Administration Sets	Disposable Infusion Set (WeiGao)	
				Both sizes are made by the same supplier as the predicate with the same material. All tubing sizes meet the performance requirements of ISO 8536-4 therefore the difference does not raise any new issues of safety and effectivity.
	Injection site (needle-free)	Y injection site PC & ABS with silicone port ISO 8536-4 ANSI/AAMI CN 27 ISO 10993-1	None.	Different. The needle-free injection site is an additional input source which is an industry standard component standardized to ISO 8536-4 & ANSI/AAMI CN 27. The testing to ANSI/AAMI CN 27 demonstrates that the product can be safely utilized without microbial ingress therefore the difference does not raise any new issues of safety and effectivity.

	Injection site (needle)	T injection site ABS with polyisoprene port ISO 8536-4 ISO 10993-1	None.	Different. The subject device includes an additional industry standard component included in the same consensus standard (ISO 8536-4) that the predicate devices are compliant to for other components. The additional component meets the performance requirements of ISO 8536-4 therefore the difference does not raise any new issues of safety and effectivity.
	Drip chamber	60 drop ABS & PVC 20 drop ABS & PVC Fiberglass vent ISO 8536-4 ISO 10993-1	60 drop ABS & PVC Fiberglass vent ISO 8536-4 ISO 10993-1	Different. Both devices include industry standard drip chambers compliant to ISO 8536-4. The additional component meets the performance requirements of ISO 8536-4 therefore the difference does not raise any new issues of safety and effectivity.
	Filter	.2 um Acrylic and Polyester (PES) / Polytetrafluoroethylenes (PTFE) ISO 8536-4 ISO 10993-1	200 ums unknown ISO 8536-4 ISO 10993-1	Different. The filters are both intended to remove particulate. Both are compliant to the same standard, ISO 8536-4. The smaller filter size meets the performance requirements of ISO 8536-4 therefore the difference does not raise any new issues of safety and effectivity.
	Burette	PETG + ABS + PVC ISO 8536-5 ISO 10993-1	None.	Different. The burette is an additional input source which is an industry standard component standardized to ISO 8536-5. The additional component meets the performance requirements of ISO 8536-5 therefore the difference does not raise any new issues of safety and effectivity.
	Spike	ABS ISO 8536-4 ISO 10993-1	ABS ISO 8536-4 ISO 10993-1	Different. The component is sourced from a different supplier. Both devices include industry standard spikes compliant to ISO 8536-4 with geometry and materials compliant to ISO 8536-4 and ISO 10993-1 and therefore the difference does not raise any new issues of safety and effectivity.
	Check valve	ABS ISO 8536-12 ISO 10993-1	None	Different. The subject device includes an additional industry standard

				component which is which is standardized to ISO 8536-12. The additional component meets the performance requirements of ISO 8536-4 therefore the difference does not raise any new issues of safety and effectivity.
	Connectors	Luers (male, female) • Female Luer w/ Cap PC + PP • Male Luer Lock w/ Cap ABS, PP ISO 594/ISO 80369-7 ISO 10993-1	Infusion needle ISO 10993-1	Different. In the proposed device, Luers are used to attach the administration set to the luer connection of a needle or catheter inserted into the vein (separate device), whereas in the predicates, the infusion needle is pre attached to the luer of the IV set. The absence of the infusion needle does not change the intended use of the device as the device will be attached to a needle or catheter for use. The difference does not raise any new issues of safety and effectivity. Since there is no needle on the subject device, the subject device is considered an indirect blood contact device, whereas the predicate with needle is a direct blood contact device. As such, the biocompatibility category of the subject device is lower (indirect blood vs direct blood) so certain biocompatibility testing completed for the predicate device (direct hemolysis testing) is not applicable to the subject device.
	Priming volume	Primary Set: 12.9 mL Burette Set: 12.9 mL Extension Set: 2.7 mL Tee Set: 0.5 mL Flow Control Set: 3.2 mL ISO 8536-4	Approximately 12-13 mL ISO 8536-4	Different. The subject devices include a wider range of priming volumes. Set sizing is based on clinical uses. The complete set meets the performance requirements of ISO 8536-4 therefore the difference does not raise any new issues of safety and effectivity.
	Residual Volume in Needless Access Port	Microclave: 0.04 mL ISO 8536-4 ANSI/AAMI CN 27 ISO 10993-1	N/A	Different. The subject adds a needleless access valve. The needle-free injection site is an additional input source which is standardized to ISO 8536-4 & ANSI/AAMI CN 27.

				The subject device has a low residual volume which is included on the label. Additionally, site protocols require flushing after needleless access port use. Therefore, the difference does not raise any new issues of safety and effectivity.

1.7 NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

Performance Testing:

The sterile single use Ecomed Disposable Administration Sets described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 8536-4 :2019, Infusion equipment for Medical Device Use- Part 4: Infusion sets for single use gravity feed.
- ISO 8536-5:2004 Burette infusion sets for single use, gravity feed.
- ISO 8536-12:2021 Infusion equipment for medical use — Part 12: Check valves for single use
- ISO 8536-13:2016 Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact
- ISO 8536-14:2016 Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

Sterilization, Packaging, Shelf-life Testing:

Sterilization is validated per ISO 11135: 2014: the device is sterilized via ethylene oxide (EO) with a minimum Sterility Assurance Level of SAL of 10-6. A total of five (5) process cycles were conducted during the execution of the product validation; one (1) sub lethal fractional exposure cycle, three (3) half exposure cycles, and one (1) full exposure cycle was executed. EO residuals were evaluated per ANSI/AAMI/ISO 10993-7:2008 and found to be acceptable.

- The products have a 2 year shelf-life that is confirmed via accelerated aging executed via ASTM F1980-07 (Reapproved 2011), standard guide for accelerated aging of sterile barrier systems for medical devices and Sterile Barrier Packaging Testing.
- Sterile Barrier Packaging Testing performed on the proposed subject device in accordance with ISO 11607-1 packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)] including the following tests:
    - Visual inspection

- Seal strength
- Dye penetration

Microbial ingress testing for the needle-free access site was performed as per ANSI AAMI CN27 Annex B.17 for microbial ingress testing.

Biocompatibility testing:

The biocompatibility evaluation was conducted in accordance with 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"* published June 16, 2016. This device is categorized in *ISO 10993-1:2009* as "External communicating device -blood path, indirect" per section 5.2.2(a). The device will have prolonged contact is likely to exceed 24 hours but not 30 days. Testing completed on this device includes:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Toxicity
- Pyrogenicity
- Hemocompatibility

Modified drug solution particulate test USP <788> was completed to confirm device particulate level.

Conclusion:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The (Ecomed Disposable Administration Sets) is substantially equivalent to the Weigao Disposable Infusion Set with respect to the indications for use, target population, and technological characteristic.