April 2, 2025

ICU Medical Inc
Yuliya Matlin
Sr. Director of Regulatory Affairs
600 N. Field Drive
Lake Forest, Illinois 60045

Re: K242114
Trade/Device Name: Plum Solo™ Precision IV Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: March 4, 2025
Received: March 5, 2025

Dear Yuliya Matlin:

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,

Rebecca Dorsey -S

For
Jake Lindstrom, 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.

Submission Number *(if known)*

K242114

Device Name

Plum Solo™ Precision IV Pump

Indications for Use *(Describe)*

The Plum Solo™ Precision IV Pump is intended for administration of parenteral fluids, medications, and whole blood and blood products through the following routes of administration: intravenous, intra-arterial, and subcutaneous.

The Plum Solo™ Precision IV Pump is intended for use in clinical environments in the hospital and other outpatient healthcare facilities by licensed healthcare professionals. These healthcare professionals are trained in the use of the infusion pump and the administration of therapies consistent with the intended use.

The Plum Solo™ Precision IV Pump is intended for adults, pediatric (including infants and children), and neonatal patient populations.

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.

510(k) Summary – K242114

This 510(k) Summary is prepared in accordance with the requirements of 21 CFR Part 807.92.

Submitter Information	
Name	ICU Medical, Inc
Address	600 North Field Drive, Lake Forest, IL 60045
Phone Number	224- 706-2419
Name Establishment Registration Number	3013319212
Name of contact person	Yuliya Matlin, MS, MBA
Date prepared	March 26, 2025
Name of device	
Trade or proprietary name	Plum Solo™ Precision IV Pump
Common or usual name	Infusion Pump
Classification	II
Classification Reason	21 CFR 880.5725
Panel	80
Product Code(s)	FRN
Legally marketed device(s) to which equivalence is claimed	Plum Duo™ Infusion System (K223607)
Reason for 510(k) submission	The submission is the traditional pre-market notification for next generation of Plum family devices Plum Solo™ Precision IV Pump
Device description	The Plum Solo™ Precision IV Pump is a large volume pump (LVP) with one pump channel that can deliver fluid to a patient from 1 to 2 lines independently. The Plum Solo™ Precision IV Pump can only be used with dedicated PlumSet™ administration sets (not subject of this filing). The pump channel accepts a cassette that is part of a PlumSet™ administration set and can connect to a primary and/or secondary container. The fluid is delivered from the upstream lines either serially (piggyback) or concurrently through the cassette to the downstream line. The flow rate accuracy precision has been improved (lower allowed variance) by implementing the new motor mechanism, as well as increased precision for programming concentration, flow rate and VTBI entries. The overall delivery accuracy of the system has improved to +/- 3% per TIR 101 standard condition testing and +/-5% for non- standard conditions.
Intended Use of Device/Indication for Use	The Plum Solo™ Precision IV Pump is intended for administration of parenteral fluids, medications, and whole blood and blood products through the following routes of administration: intravenous, intra-arterial, and subcutaneous. The Plum Solo™ Precision IV Pump is intended for use in clinical environments in the hospital and other outpatient healthcare facilities by licensed healthcare professionals. These healthcare professionals are trained in the use of the infusion pump and the administration of therapies consistent with the intended use. The Plum Solo™ Precision IV Pump is intended for adults, pediatric (including infants and children), and neonatal patient populations.

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Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate *(K223607)***	**Comparison**
Device Name	Plum Solo™ Precision IV Pump	Plum Duo™ Infusion System	N/A
Type of Pump	Large Volume Infusion Pump		Same
Intended Use/Indications for Use	The Plum Solo™ Precision IV Pump is intended for administration of parenteral fluids, medications, and whole blood and blood products through the following routes of administration: intravenous, intra-arterial, and subcutaneous. The Plum Solo™ Precision IV Pump is intended for use in clinical environments in the hospital and other outpatient healthcare facilities by licensed healthcare professionals. These healthcare professionals are trained in the use of the infusion pump and the administration of therapies consistent with the intended use. The Plum Solo™ Precision IV Pump is intended for adults, pediatric (including infants and children), and neonatal patient populations.	The Plum Duo Infusion System is intended for parenteral fluids and medications through clinically acceptable routes (limited to intravenous, intra-arterial, and subcutaneous therapies). The Plum Duo Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations.	Substantially equivalent
Patient Population	The Plum Solo Precision IV Pump is intended for adult, pediatric (including infants and children), and neonatal patient populations.	The Plum Duo Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations.	No change to the intended population.
Environment of Use	Hospital environments and other outpatient healthcare facilities that exclude hyperbaric or oxygen-rich environments. Not for MRI environment. The Plum Solo Precision IV Pump is intended for use in clinical environments in the hospital and other outpatient healthcare facilities by licensed healthcare professionals. These healthcare professionals are trained in the use of the infusion pump and the administration of therapies consistent with the intended use.		Same
Route of Administration	Intravenous, intra-arterial, and subcutaneous.	Parenteral, (limited to intravenous, subcutaneous, and intra-arterial therapies).	Same
Set Compatibility	Compatible with currently marketed Plum™ Administration Sets		Same

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate *(K223607)***	**Comparison**
ICU Medical Safety Software/Drug Library	Compatible with ICU Medical LifeShield™ Infusion Safety Software Suite		Same
Drug Library	Custom Drug Library (CDL) (automatically opt-in upon start of programming) No Default Drug Library (DDL)		Same
Delivery Methods/ Therapies	1. Continuous 2. Multistep 3. Loading Dose (standalone or with underlying continuous therapy) 4. Bolus (standalone or with underlying continuous therapy)		Same
Therapy Modes	1. Piggyback • optional flush feature • optional Infuse to Empty feature for medications configured as intermittent in the drug library 2. Concurrent • optional disablement of VTBI Complete alarm for medications configured as intermittent in the drug library 3. Deliver alone (primary delivery only)	1. Piggyback (optional flush feature) 2. Concurrent 3. Deliver alone (primary delivery only)	Substantially Equivalent The addition of the piggyback optional Infuse to Empty feature is an automation of the existing manual workflow and ensures the patient receives the entire piggyback medication at the programmed rate, including the volume of the upstream tubing. The addition of the concurrent optional disablement of VTBI Complete alarm for medications configured as intermittent in the drug library allows the clinician to disable the VTBI Complete Alarm when no further secondary infusion in concurrent mode is required. No impact on Safety and Effectiveness.
Rate Ranges	• 0.1 to 9.99 mL/hr (in 0.01 mL/hr increments) • 10. to 99.9 mL/hr (in 0.1 mL/hr increments) • 100 to 999 mL/hr (in 1 mL/hr increments)	• 0.1 to 99.9 mL/hr (in 0.1 mL/hr increments) • 100 to 999 mL/hr (in 1 mL/hr increments)	Substantially equivalent The higher precision rate entry at the low-rate range gives the clinician greater precision and flexibility to tailor the therapy to meet the patient's specific medical needs.
Bolus and Loading Dose Rate Ranges	• 0.1 to 9.99 mL/hr (in 0.01 mL/hr increments) • 10 to 99.9 mL/hr (in 0.1 mL/hr increments) • 100 to 999 mL/hr (in 1 mL/hr increments)	• 0.1 to 99.9 mL/hr (in 0.1 mL/hr increments) • 100 to 999 mL/hr (in 1 mL/hr increments)	Substantially equivalent The higher precision rate entry at the low-rate range gives the clinician greater precision and flexibility to tailor the therapy to meet the patient's specific medical needs.

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Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate *(K223607)***	**Comparison**
Flow Rate Delivery Accuracy	• 0.1 - 999 mL/hr: +/- 3% • 0 to 96 hours of cassette service Bolus delivery accuracy is +/-5% for delivery volumes as low as 0.1 ml at 999 ml/hr.	• 0.1 - 999 mL/hr: +/- 5% • 0 to 96 hours of cassette service Bolus delivery accuracy is +/-5% for delivery volumes as low as 0.1 ml at 999 ml/hr.	Substantially equivalent Flow rate accuracy improvements provide greater precision of delivery.
WiFi	Yes		Same
Pump Operation	Volumetric Piston Type		Same
Number of Channels	1 Channel: Right channel has primary (Line 1) and secondary (Line 2)	2 Channels: Left and Right Channel. Each channel has primary (Line 1) and secondary (Line 2)	Substantially equivalent
Sensors	Air detection, Occlusion, Temperature, Cassette detection, Ambient light sensors		Same
Alarm Summary	Check cassette alarms, proximal (upstream) and distal (downstream) occlusion, door open, air detection, callback, lockout, low battery, and internal system monitor alarms.		Substantially equivalent. Subject device has enhanced air detection alarms.
Clinical Advisories	Optional clinical advisory field/message on the pump interface. Cannot be configured or disabled by pump user.		Same
Operating Environment and Storage Specifications	Operating Temperature: 41°F to 104°F (5°C to 40°C) Storage Temperature: -4°F to 140°F (-20°C to 60°C) Atmospheric Pressure: 0 to 10,000 feet (0 to 3000 meters) or equivalent atmospheric pressure Relative Humidity: 10% to 90% (maximum dew point of 30°C)		Same Details are located in the product labeling

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Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate *(K223607)***	**Comparison**
Physical Specifications	Single Channel Device: Dimensions: Approximately 8.5 H x 6.5 W x 6.5 D inches 21.6 cm H x 16.5 cm W x 16.5 cm D) (excluding pole clamp extrusion and power cord storage) Mass: Approximately 7 lbs (3.2 kg) with battery Casing: High-impact plastic.	Two Channel Device: Duo Dimensions: Approximately 9 H x 11.75 W x 6.5 D inches (23 cm H x 30 cm W x 17 cm D) (excluding pole clamp extrusion and power cord storage) Mass: Approximately 10.6 lbs (4.8 kilograms) with battery Casing: High-impact plastic.	Substantially equivalent
Power Requirements	Off the Shelf (OTS) universal power supply acceptable for 100 to 240 VAC, 50-60 Hz mains supply.		Same
Battery	Lithium Iron Phosphate Battery (2500mAhr) with battery management electronics. Battery life greater than 2 years.	Lithium Iron Phosphate Battery (3000 mAhr) with battery management electronics. Battery life greater than 2 years.	Substantially equivalent
Display	7” color display with WXGA resolution and Gorilla glass to protect LCD.	10.1” color display with WXGA resolution and Gorilla glass to protect LCD.	Substantially equivalent

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Summary of Non-Clinical Testing

To demonstrate substantial equivalence between the subject and predicate device the following non-clinical tests were performed:

- Verification testing of product requirements
- Human factors validation testing of product requirements associated with critical tasks
- Testing for the reliability goals of the device

The safety assurance case was provided for the Plum Solo™ Precision IV Pump as recommended in the FDA Guidance document, *Infusion Pumps Total Product Life Cycle* issued December 2, 2014.

The safety assurance case is used to build a robust argument that the Plum Solo™ Precision IV Pump is safe for its intended use in its intended environment. The argument is made by mitigating the following three arguments wherein risk may be produced within the context of the device' intended use.

The assurance case defines the device system, including the operational description, system definition, indications for use, patient population, intended users and use environments. The supporting assurance arguments covered the following attributes:

- Plum Solo™ Precision IV Pump hazards are adequately identified and addressed.
- Plum Solo™ Precision IV Pump design is adequately reliable.
- Plum Solo™ Precision IV Pump design requirements are adequate and are adequately verified and validated.

The following evidence was included in the safety assurance case:

- Design verification and validation testing confirmed the Plum Solo™ Precision IV Pump met user needs, risk controls, and design inputs. Testing results conformed with acceptance criteria.
- Flow rate and bolus accuracy testing were conducted by following *AAMI TIR101*.
- Device reliability activities, testing and statistical analysis confirmed the Plum Solo™ Precision IV Pump met its reliability goal at the system, device subsystem, and subsystem component level.
- Software verification and validation were performed per FDA Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices* issued May 11, 2005, and *Content of Premarket Submissions for Device Software Functions Draft Guidance for Industry and Food and Drug Administration Staff*, issued November 4, 2021.
- Human factors evaluations were conducted to validate the effectiveness of safety critical use-related features/functionality and use error-related mitigations in the associated use environments. The 2016 FDA guidance document, *Applying Human Factors and Usability Engineering to Medical Devices*, and *IEC 62366-1 Medical Devices Part 1: Application of usability engineering to medical devices* were followed.

Electrical and Electromagnetic Compatibility testing were conducted. The Plum Solo™ Precision IV Pump complies with the following standards:

- Electrical Safety per *IEC 60601-1* and Electromagnetic Compatibility per *IEC 60601-1-2.*

Cybersecurity testing performed confirmed the system is effective in addressing cybersecurity threats. FDA Cybersecurity Guidance followed during development include *Content of Premarket Submissions for Management of Cybersecurity*, issued October 2, 2014 and *Postmarket Management of Cybersecurity in Medical Devices*, issued December 28, 2016.

Risk management activities have been incorporated into the design in accordance with *ISO 14971:2019 +A11 2021* and have been tested for correct implementation and effectiveness as part of design verification and validation

Clinical Testing
Clinical evaluation is not required for this submission to support substantial equivalence.

Conclusion
The differences between the predicate and subject device do not raise different questions of safety or effectiveness. The Plum Solo™ Precision IV Pump is substantially equivalent to the predicate device Plum Duo™ Infusion System (K223607).