August 24, 2023

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

Re: K223607
Trade/Device Name: Plum Duo™ Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: July 27, 2023
Received: July 28, 2023

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 (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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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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)*
K223607

Device Name
Plum Duo™ Infusion System

Indications for Use *(Describe)*

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 use in clinical environments in the hospital environment 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 Duo Infusion System is intended for adult, 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.

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510(k) Summary

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 880.5725 for Plum Duo™ Infusion System is provided below.

Submitter Information	
Name	ICU Medical, Inc
Address	600 North Field Drive Lake Forest, IL. 60045
Phone number	224- 706-2419
Fax number	N/A
Establishment Registration Number	3013319212
Name of contact person	Yuliya Matlin, MS., MBA yuliya.matlin@icumed.com
Date prepared	July 27, 2023
Name of device	
Trade or proprietary name	Plum Duo™ Infusion System
Common or usual name	Infusion Pump
Classification	II
Classification Reason	21 CFR 880.5725
Panel	80
Product Code(s)	FRN
510(k) Number	K223607
Legally marketed device(s) to which equivalence is claimed	Plum 360™ Infusion System with MedNet/ Smart Card Plug 'n' Play Module
Reason for 510(k) submission	The submission is the traditional pre-market notification for the next generation of the Plum family of Devices: Plum Duo™ Infusion System
Device description	The Plum Duo™ Infusion System is the next generation of the Plum™ family of devices that is based on the fundamental technology of the Plum 360™ Infusion System cleared under K161469. The pump design incorporates state-of-the-art features such as dual channel functionality, touch screen display, and lithium iron phosphate battery technology. The pump uses the same volumetric piston type technology with a plunger stepper motor to deliver fluids to a patient as the predicate Plum 360™ Infusion System. Plum Duo™ Infusion System is a large volume pump (LVP) with two independent pump channels that can deliver fluid to a patient on up to 4 lines and is designed so that it is possible to use one channel only. In addition, although the channels can operate independently, patient parameters can be shared across the channels to aid in the speed of programming. Each channel accepts a cassette that is part of a PlumSet™ administration set and can connect to a primary and/or secondary container.
Intended Use of Device/Indication for Use	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 use in clinical environments in the hospital environment 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 Duo Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device (K223607)**	**Predicate *(K161469)***	**Comparison**
Device Name	Plum Duo™ Infusion System	Plum 360™ Infusion System with MedNet™ / Smart Card Plug 'n' Play Module	N/A
Type of Pump	Large Volume Infusion Pump		Same
Intended Use/Indications for Use	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 use in clinical environments in the hospital environment 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 Duo Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations. .	The Plum 360™ Infusion System with MedNet™ / Smart Card Plug 'n' Play Module is intended for use in parenteral, enteral, and epidural therapies and the administration of whole blood and blood products.	Similar Additional details are added to the intended use statement of the subject device to clarify patient populations and the meaning of parenteral routes of administration. Both the predicate device and the subject device are prescription devices. They are both infusion pump systems indicated for use in parenteral therapies. ICU Medical is removing the enteral and epidural routes of administration as well as the administration of whole blood and blood products from the indications for use for the Plum Duo Infusion System. The indications are limited to the subset of the predicate device indications for use.
Patient Population	The Plum Duo Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations.	Not Specified	No change in the intended patient population. Additional details added to the statement to clarify the patient population.
Environment of Use	Hospital environments and other outpatient healthcare facilities that excludes hyperbaric or oxygen-rich environments. Not for MRI environment. The Plum Duo Infusion System is intended for use in clinical environments in the hospital environment and other outpatient healthcare facilities by licensed healthcare professionals. These healthcare professionals are trained in	Hospital environments and other outpatient healthcare facilities that excludes hyperbaric or oxygen-rich environments. Not for MRI environment. The Plum Duo Infusion System is intended for use in clinical environments in the hospital environment and other outpatient healthcare facilities by licensed healthcare professionals. These	Similar The subject device is used in the same environment (hospitals and other healthcare facilities). The statement has been aligned with the intended use.

Summary of the technological characteristics of the device compared to the predicate device			
	the use of the infusion pump and the administration of therapies consistent with the intended use.	healthcare professionals are trained in the use of the infusion pump and the administration of therapies consistent with the intended use. In addition, the healthcare professionals are trained in the administration of whole blood and blood products.	
Route of Administration	Parenteral, limited to intravenous, subcutaneous, and intra-arterial.	Parenteral, enteral and epidural	Similar The subject device routes of administration are a subset of the predicate device routes of administration and are consistent with the predicate.
Set Compatibility	Compatible with currently marketed Plum™ Administration Sets		Same
ICU Medical Safety Software/Drug Library	Compatible with LifeShield™ Infusion Safety Software Suite	Compatible with ICU Medical MedNet™ Safety Software	Similar Both products are compatible with Infusion Safety Software.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device (K223607)**	**Predicate *(K161469)***	**Comparison**
Drug Library	Custom Drug Library (CDL) No Default Drug Library (DDL)	Custom Drug Library and Default Drug Library	Similar Removing the option of default drug library increases compliance with the usage of the hospital created drug library.
Delivery Methods/ Therapies	1. Continuous 2. Multistep 3. Loading Dose (standalone or with underlying continuous therapy) 4. Bolus (standalone or with underlying continuous therapy)	1. Continuous 2. Multistep 3. Loading Dose (with underlying continuous therapy) 4. Bolus (with underlying continuous therapy)	Similar The ability to deliver a loading dose and/or bolus without an underlying continuous therapy allows the clinician additional flexibility in administering therapy.
Therapy Modes	1. Piggyback (with flush feature) 2. Concurrent 3. Deliver alone (primary delivery only)	1. Piggyback 2. Concurrent	Similar The addition of the piggyback flush feature automates the existing manual workflow and ensures the patient receives the piggyback medication in its entirety at the piggyback delivery rate for the duration of the therapy. The addition of deliver alone provides an additional option for the medications that should not be interrupted or delivered concurrently with another medication or fluid.
Rate Ranges	0.1 to 99.9 mL/hr (in 0.1 mL/hr increments) 100 to 999 mL/hr (in 1 mL/hr increments)		Same
Bolus Rate Ranges	0.1 to 99.9 mL/hr (in 0.1 mL/hr increments) 100 to 999 mL/hr (in 1 mL/hr increments)	1.0 to 99.9 mL/hr (in 0.1 mL/hr increments) 100 to 999 mL/hr (in 1 mL/hr increments)	Similar The extended range provides greater flexibility to the clinician to tailor the therapy to meet the patient's specific medical needs.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device (K223607)**	**Predicate *(K161469)***	**Comparison**
Flow Rate Delivery Accuracy	• 0.1 - 0.9 mL/hr: +/- 5%, • 1 - 999 mL/hr: +/- 5% 0 to 96 hours of cassette service	• 0.1 - 0.9 mL/hr: +/- 10%, • 1 - 999 mL/hr: +/- 5% 0 to 48 hours of cassette service	Similar Detailed flow rate accuracy disclosed in the labeling
WiFi	Yes		Same
Pump Operation	Volumetric Piston Type		Same
Number of Channels	2 Channels: Left and Right Channel. Each channel has primary (Line 1) and secondary (Line 2)	Single channel with primary (Line A) and secondary (Line B)	Similar The addition of the second channel enables the clinician to infuse four therapies simultaneously on one device. The ability to add additional infusion lines on the same device allows more efficiency in space management and ease of line management with tracing to one device.
Sensors	Air Detection, Occlusion, Temperature, Cassette Detection, Ambient light sensors	Air Detection, Occlusion, Cassette Detection sensors	Similar Additional sensor functionality optimizes system performance.
Alarm Summary	Check cassette alarms, proximal (upstream) and distal (downstream) occlusion, door open, air detection, callback, lockout, low battery, and internal system monitor alarms.		Same
Clinical Advisories	Addition of the clinical advisory field/message on the pump interface	Not available	Different This feature provides an additional field for the pharmacy to enter any applicable precautions or instructions

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device (K223607)**	**Predicate *(K161469)***	**Comparison**
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
Physical Specifications	**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.	**Dimensions:** Approximately 8” H x 8” W x 6” D (20 cm H x 20 cm W x 15 cm D), excluding pole clamp extrusion and power cord storage. **Mass:** Approximately 10 lbs. (4.5 kg) with battery **Casing:** High-impact plastic.	Similar The differences in physical dimensions do not impact ergonomics or user experience.
Power Requirements	Off the Shelf (OTS) universal power supply acceptable for 120v and 240v mains supply	ICU Medical design: Separate power supplies for US (120v) and international (240v) configurations	Similar Universal power supply provides customer convenience to use uniform power source.
Battery	Lithium Iron Phosphate Battery with battery management electronics	Sealed Lead Acid Battery	Different Updated battery technology to improve power density, battery capacity reporting, and safety monitoring reliability and life cycle for optimization of performance.
Display	10" color touchscreen display with WXGA resolution	Custom 4" QVGA Monochromatic display	Different Full color touchscreen display with increased resolution enhances the user experience.

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 Duo™ Infusion System 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 Duo™ Infusion System 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's 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 Duo™ Infusion System hazards are adequately identified and addressed.
- Plum Duo™ Infusion System design is adequately reliable.
- Plum Duo™ Infusion System design requirements are adequate and are adequately verified and validated.

Verification and validation testing was completed in support of this premarket submission. The following table provides a summary of the testing:

Flow Rate Accuracy Testing
Flow Continuity
Flow Rate Accuracy (Primary and Secondary Delivery)
Backpressure Delivery
Concurrent Delivery
Multistep Delivery
Clinically Relevant Combination of Factors (non-standard operating conditions)
AAMI TIR 101 Testing
Start Up Delay Time and Flow Rate Accuracy
Loading Dose Volumetric Accuracy
Bolus Volumetric Accuracy
Flow Reduction due to Inline Resistance
Air In Line Performance Testing
Upstream Single Air Bolus
Downstream Single Air Bolus
Upstream Cumulative Air-In-Line
Downstream Cumulative Air-in-Line
Cassette Performance Testing
Free Flow Protection

Cassette loading and unloading
Backpriming
Cassette Integrity Check
Occlusion Performance Testing
Time to Detect Downstream Occlusion
Maximum Unintended Bolus after Occlusion resolved
Downstream Occlusion Auto Restart
Upstream/Downstream Occlusion
Alarms Testing Functional, Audio, Visual, Software testing of system's alarms
Mechanical/Hardware Testing
Touchscreen Display Functionality
Door Functionality
Infuser Sound Levels
IV Pole Configuration and Stability
Physical Attributes (power cord, grip handle, pump dimensions/weight)
Pole Clamp Functionality
Fluid Ingress Testing
Environmental conditions testing
Operating Temperature
Storage Temperature
Atmospheric Pressure
Relative Humidity
Packaging
Shipping and Packaging
Shock and Vibration
Electrical Platform Testing
Electrical Design Analysis
Electrical Subsystem Functional
Electrical Subsystem Performance
Battery Testing
Battery System Design Analysis
Battery Functionality and Performance
Battery Run Time
Battery Certification
Material Compatibility (Cleaning and Disinfection Agents) Testing
Functional/ Cleaning and Disinfection
Validation of Reprocessing Instructions Testing
Functional/ Cleaning and Disinfection
Certifications
IEC 60601 Series Certification (IEC 60601-1, IEC 60601-1-8, IEC 60601-1-6, IEC 62304, IEC 62366-1)
CE Performance Testing
CE Subsystem Design Analysis

CE Functionality
FCC Certification
EMI / EMC Testing
Radiated and Conducted Emissions/ Immunity
Voltage Variation Immunity
Magnetic Field Immunity
Surge, ESD, RFID, Electrical Fast Transient (EFT) Immunity
Multiple Pump EMI and Wireless Coexistence Evaluation
Cybersecurity Testing
Software Verification and Validation: code inspection, unit testing, static analysis, black / grey box testing, system integration testing
Reliability Testing
Cassette Loader Reliability
Battery Reliability
Pressure Sensor Reliability
Pole Clamp Reliability
Power Button Reliability
Display Reliability
Circuit Board Reliability
Power Supply Reliability
Haptics Reliability
Speaker Reliability
Battery Cell Storage Reliability
Backup Piezo Reliability
Mechanism Reliability
Preventive Maintenance Analysis
HALT (Highly Accelerated Life Test) Reliability
Free Fall Drop Abuse
Display Impact Reliability
AC Power Cord and Retainer Abuse
Thermal Margin Analysis
Software Reliability
Human Factors Validation Testing
Interoperability
Auto-programming and Auto-documentation

- Design verification and validation testing confirmed the Plum Duo™ Infusion System 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 Duo™ Infusion System 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. *IEC 62366-1 Medical Devices Part 1: Application of usability engineering to medical devices* was followed.

Electrical and Electromagnetic Compatibility testing were conducted. The Plum Duo™ Infusion System 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* 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 the subject device do not raise any new or different questions of safety or effectiveness. The Plum Duo™ Infusion System is substantially equivalent to the Plum 360™ Infusion System with MedNet™ / Smart Card Plug 'n' Play Module cleared under K161469 with respect to the indications for use, target populations, treatment method, and technological characteristics.