April 2, 2025

ICU Medical, Inc.
Pernell Abrantes
Director of Regulatory Affairs
600 North Field Drive
Lake Forest, Illinois 60045

Re: K242117
Trade/Device Name: LifeShield™ Infusion Safety Software Suite
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PHC
Dated: February 28, 2025
Received: March 5, 2025

Dear Pernell Abrantes:

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.

510(k) Number *(if known)*
K242117

Device Name
LifeShield™ Infusion Safety Software Suite

Indications for Use *(Describe)*
The LifeShield™ Infusion Safety Software Suite is a collection of software products that facilitates networked communication between compatible systems. The Infusion Safety Software Suite provides trained healthcare professionals the ability to manage data for compatible infusion pumps. All data entry and validation of infusion parameters on compatible infusion pumps is performed by a trained healthcare professional. LifeShield™ Infusion Safety Software Suite is indicated for use in patients including adult, pediatric and neonate undergoing infusion therapy with connected compatible infusion pumps (as per the indications for use specified for the compatible infusion pump).

The LifeShield™ Drug Library Management (DLM) software product is intended to be used by pharmacists to create, configure, edit, and manage drug library data, including infusion pump settings, for use with compatible infusion pumps. Drug library contents are constructed based on the healthcare provider's defined best practices.

The LifeShield™ Clinical Dashboards & Reports (CDR) software product provides trained healthcare professionals with the capability to view and manage infusion information collected from compatible infusion pumps. Healthcare professionals may choose to use the collected infusion information to support continuous quality improvement programs, or to analyze and trend various aspects of the infusion pumps and therapies used. It is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

The LifeShield™ Data Flow Management (DFM) software product is intended to facilitate bi-directional communication with compatible infusion pumps, information technology systems, and other LifeShield™ Infusion Safety Software Suite products. LifeShield™ DFM provides a way to automate the programming of infusion parameters, thereby decreasing the number of manual steps necessary to enter infusion data. LifeShield™ DFM forwards infusion-related information received from the infusion pump to compatible information technology systems.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K242117

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
Establishment Registration Number	3013319212
Name of contact person	Pernell Abrantes
Phone number	(224) 706-2229
Date prepared	March 24, 2025
Name of device	
Trade or proprietary name	LifeShield™ Infusion Safety Software Suite
Common or usual name	Infusion Safety Management Software
Classification	Class II
Regulation	21 CFR 880.5725
Panel	General Hospital
Product Code(s)	PHC
Predicate Device	K223606, LifeShield™ Infusion Safety Software Suite
Reason for 510(k) submission	The submission is a traditional pre-market notification for software modifications made to LifeShield™ Infusion Safety Software Suite.
Device description	The LifeShield™ Infusion Safety Software Suite is a cloud-based platform provided as a software-as-a-service (SaaS) designed to be compatible with the Plum Duo™ Precision IV infusion pump and Plum Solo™ Precision IV infusion pump. The LifeShield Infusion Safety Software Suite is hosted by Amazon Web Services (AWS) as its cloud provider. LifeShield™ Infusion Safety Software Suite consists of a collection of software services which, when used together, provide a comprehensive set of data management capabilities for trained healthcare professionals when working with infusion pumps. LifeShield™ Infusion Safety Software Suite does not remotely control or program the infusion pump or provide the ability to remotely manage pump alarms such as real-time monitoring, clearing and silencing alarms. The LifeShield™ Drug Library Management (DLM) software is used by pharmacists to create approved drug libraries that can be downloaded by the infusion pumps. The latest software version introduces enhancements

	to its user interface and additional drug library settings for support of Plum Duo™ and Plum Solo™ pumps. The LifeShield™ Clinical Dashboards & Reports (CDR) software is used by clinical administrators to view infusion or device-related information received from the infusion pumps via the LifeShield™ DFM. The information presented by the software does not create decisions or treatment pathways for patients. The latest version of the software improves the data presented for ongoing infusions and dashboards. LifeShield™ Data Flow Management (DFM) software facilitates bi-directional communications between the infusion pump and hospital information systems (HIS); it routes pharmacy-validated orders to the connected pumps and infusion-related information to the HIS. The latest software version adds the ability to forward alarms to the HIS.
Intended Use of Device/Indication for use	The LifeShield™ Infusion Safety Software Suite is a collection of software products that facilitates networked communication between compatible systems. The Infusion Safety Software Suite provides trained healthcare professionals the ability to manage data for compatible infusion pumps. All data entry and validation of infusion parameters on compatible infusion pumps is performed by a trained healthcare professional. LifeShield™ Infusion Safety Software Suite is indicated for use in patients including adult, pediatric and neonate undergoing infusion therapy with connected compatible infusion pumps (as per the indications for use specified for the compatible infusion pump). The LifeShield™ Drug Library Management (DLM) software product is intended to be used by pharmacists to create, configure, edit, and manage drug library data, including infusion pump settings, for use with compatible infusion pumps. Drug library contents are constructed based on the healthcare provider's defined best practices. The LifeShield™ Clinical Dashboards & Reports (CDR) software product provides trained healthcare professionals with the capability to view and manage infusion information collected from compatible infusion pumps. Healthcare professionals may choose to use the collected infusion information to support continuous quality improvement programs, or to analyze and trend various aspects of the infusion pumps and therapies used. It is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways. The LifeShield™ Data Flow Management (DFM) software product is intended to facilitate bi-directional communication with compatible infusion pumps, information technology systems, and other LifeShield™ Infusion Safety Software Suite products. LifeShield™ DFM provides a way to automate the programming of infusion parameters, thereby decreasing the number of manual steps necessary to enter infusion data. LifeShield™ DFM

	forwards infusion-related information received from the infusion pump to compatible information technology systems.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
Indications for Use	The LifeShield™ Infusion Safety Software Suite is a collection of software products that facilitates networked communication between compatible systems. The Infusion Safety Software Suite provides trained healthcare professionals the ability to manage data for compatible infusion pumps. All data entry and validation of infusion parameters on compatible infusion pumps is performed by a trained healthcare professional. LifeShield™ Infusion Safety Software Suite is indicated for use in patients including adult, pediatric and neonate undergoing infusion therapy with connected compatible infusion pumps (as per the indications for use specified for the compatible infusion pump). The LifeShield™ Drug Library Management (DLM) software product is intended to be used by pharmacists to create, configure, edit, and manage drug library data, including infusion pump settings, for use with compatible infusion pumps. Drug library contents are constructed based on the healthcare provider's defined best practices. The LifeShield™ Clinical Dashboards & Reports (CDR) software product provides trained healthcare professionals with the	The LifeShield™ Infusion Safety Software Suite is a collection of software products that facilitates networked communication between compatible systems. The Infusion Safety Software Suite provides trained healthcare professionals the ability to manage data for compatible infusion pumps. All data entry and validation of infusion parameters on compatible infusion pumps is performed by a trained healthcare professional. LifeShield™ Infusion Safety Software Suite is indicated for use in patients including adult, pediatric and neonate undergoing infusion therapy with connected compatible infusion pumps (as per the indications for use specified for the compatible infusion pump). The LifeShield™ Drug Library Management (DLM) software product is intended to be used by pharmacists to create, configure, edit, and manage drug library data, including infusion pump settings, for use with compatible infusion pumps. Drug library contents are constructed based on the healthcare provider's defined best practices. The LifeShield™ Clinical Dashboards & Reports (CDR) software product provides	Similar Subject device indications statement adds a more descriptive detail on the device purpose and functions. This does not raise different questions of safety and effectiveness.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
	capability to view and manage infusion information collected from compatible infusion pumps. Healthcare professionals may choose to use the collected infusion information to support continuous quality improvement programs, or to analyze and trend various aspects of the infusion pumps and therapies used. It is not intended to be a substitute for good clinical management practices, nor does its operation create decision or treatment pathways. The LifeShield™ Data Flow Management (DFM) software product is intended to facilitate bi-directional communication with compatible infusion pumps, information technology systems, and other LifeShield™ Infusion Safety Software Suite products. LifeShield™ DFM provides a way to automate the programming of infusion parameters, thereby decreasing the number of manual steps necessary to enter infusion data. LifeShield™ DFM forwards infusion-related information received from the infusion pump to compatible information technology systems.	trained healthcare professionals with the capability to view and manage infusion information collected from compatible infusion pumps. Healthcare professionals may choose to use the collected infusion information to support continuous quality improvement programs, or to analyze and trend various aspects of the infusion pumps and therapies used. It is not intended to be a substitute for good clinical management practices, nor does its operation create decision or treatment pathways.	
Prescription Device	Yes		Same

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
Stand-alone software or embedded software	Stand-alone		Same
Application Type	Web-based		Same
Compatible Browser	Google Chrome Microsoft Edge	Google Chrome	Similar No difference in design, function or performance of the software. This does not raise different questions of safety and effectiveness.
Database provider	Amazon Web Services Cloud		Same
Compatible Infusion Pump	Plum Duo Plum Solo	Plum Duo	Similar The subject device extends its functional support to an additional large volume pump within the ICU Medical Plum family. This does not raise different questions of safety and effectiveness.
Drug library Capacity	40 Clinical Care Areas / 40,000 total rulesets		Same
No Drug Selected	Available with program and delivery mode settings		Same

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
Drug Library Report	Single printable report		Same
Facility support	Multiple facilities for drug library and data reporting		Same
Drug Library Workflow	-ability to create new or copy existing medication rulesets -UI improvement for viewing pump family/versions, CCA settings, and status of drug library and pump software update	-ability to create new medication rulesets -ability to view status of drug library and pump software updates	Similar The subject device implemented UI enhancements to better facilitate construction and scheduling drug library updates. This does not raise different questions of safety and effectiveness.
Drug Library Settings	Updated Drug library specifications for Plum Duo™ and Plum Solo™, introducing additional settings: -auto-program rejection notice timeout -volume display on main delivery screen -single bolus air-in-line detection -enable calculation assist -program delivery method -post-infusion options (infuse to empty, infusion complete alarm disablement) -initial default values for bolus and loading dose	General Pump Settings for Plum Duo™ Program Delivery Mode CCA settings for Patient weight, height and BSA Concentration Type Therapy-based medication limits Non-Therapy based medication limits Clinical Use and Clinical Advisory High-Alert medication designation	Different The subject device enhances the drug library to add additional design mitigations, to align with configurable pump features, and to enhance user workflow. Existing design to allow review of these settings served as effective risk mitigation. This does not raise different questions of safety and effectiveness.
Therapy Mode Supported	Continuous, Intermittent, Bolus, Loading Dose, Multistep	Continuous, Bolus, Loading Dose, Multistep	Similar

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
			The additional therapy mode provides enhanced design mitigations in the drug library. This does not raise different questions of safety and effectiveness.
Medication Unit Family	grams, mL, Units, mmol, mEq		Same
Number of medication units	119		Same
Infusion and Device Status Display	Near-real time Additional data reported for pump type, program mode/source, and time remaining Dashboard reports auto-program counts	Near-real time	Similar The enhancement supports a more comprehensive infusion data available to the user. This does not raise different questions of safety and effectiveness.
Historical Reports	Accessible in LifeShield DLM, CDR and DM	Reports imported from external tool. Report availability is configurable	Similar The added location to access the reports did not change the reporting functionality. This does not raise different questions of safety and effectiveness.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
Auto-programming	Supported with enhanced authentication and content (addition of clinician acceptance of auto-program)	Supported	Similar The enhancements are to ensure a more secure connection with the hospital systems, and that hospital systems are notified of auto-program acceptance or rejection at the pump. This does not raise different questions of safety and effectiveness.
Alarm Communication	Displays in active infusion view Alarm forwarding to hospital information systems	Displays in active infusion view	Similar The addition of alarms with infusion data enhances the information forwarded to the hospital systems. This does not raise different questions of safety and effectiveness.
Infusion Documentation	Supported with enhanced content (addition of infusion data generated while pump is offline). Patient information disassociated from offline pump	Supported	Similar The enhancement supports a more comprehensive and updated infusion data that is sent to the hospital systems. This does not raise different questions of safety and effectiveness.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
Asset Management	Drug library update Pump Software update Device Status added certificate status and customizable access point description Device Log Request	Drug library update Pump Software update Device Status	Similar Additional pump data reported and feature to download pump logs to support investigations does not raise different questions of safety and effectiveness.
User access	Role-based access Local login credentials Active Directory Integration	Role-based access Local login credentials	Similar The additional feature provides customer an option for identity and access management. This does not raise different questions of safety and effectiveness.
Multi-factor Authentication	Time-based one-time password	SMS authentication	Similar The subject device employs a more secure method for multi-factor authentication. This does not raise different questions of safety and effectiveness.
Digitally-signed Drug Library	Supported		Same

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K223606**	**Comparison**
The subject and predicate devices have the same intended use and indications for use with the indications for use statement adding a more detailed description of the device's functions and purpose already supported by the predicate. Both the subject and predicate devices utilize the same fundamental software technology; the software modifications that are introduced in the subject device are iterative progression to the features and design of the predicate, enhancing the use experience and safety of the device. The risks identified due to the software modifications have been effectively mitigated. Testing confirms that the software modifications do not introduce different questions of safety and effectiveness when compared to the predicate device, and that the subject device is as safe and effective as the predicate device.			

Summary of Non-Clinical Testing

Non-clinical verification of *LifeShield™ Infusion Safety Software Suite* has been conducted to evaluate the safety, performance and functionality. The results of these tests have demonstrated its overall safety, and ultimately support a substantial equivalence determination to the predicate device. A summary of the testing conducted is presented below:

- Design verification tests pass established acceptance criteria, confirming the subject device meets design requirements. Verification activities also include software verification, performance, reliability, compatibility, and interoperability tests. Software verification follows the software development process outlined in IEC 62304:2015.
- Design validation tests pass established acceptance criteria, confirming the subject device meets all intended users' needs for the device's intended use and intended use environment.
- Cybersecurity evaluation and testing demonstrate that the software is reasonably secure.
- Risk management activities are performed in accordance with ISO 14971:2019, and risk mitigations have been incorporated into the design and have been tested for correct implementation and effectiveness as part of design verification and validation. Safety Assurance Case conducted in accordance with AAMI TIR38:2018 and FDA Guidance: *Total Product Lifecycle of Infusion Pumps* issued in 2014 concludes that the subject device is reasonably safe.
- Human Factors study demonstrates the effectiveness of the user interface design for additional features and their associated critical tasks. The human factors study was conducted in accordance with the 2016 FDA guidance document, *Applying Human Factors and Usability Engineering to Medical Devices*, IEC 62366-1:2020 and ANSI/AAMI HE75:2009/(R)2018.

Summary of Clinical Testing

Not applicable. A clinical study is not required for this submission to support substantial equivalence.

Conclusion

The subject device, *LifeShield™ Infusion Safety Software Suite,* is as safe and effective for its intended use as the currently marketed predicate device. Verification, validation, cybersecurity and human factors testing conducted demonstrate that subject device meets all acceptance criteria requirements, and confirm that no different questions of safety and effectiveness are raised. Therefore, the subject device, *LifeShield™ Infusion Safety Software Suite,* is substantially equivalent to the currently marketed predicate device.