



April 2, 2026

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

Re: K252130

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 25, 2025  
Received: February 25, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jake K. Lindstrom -S**

Jake Lindstrom, Ph.D.

Assistant Director, Infusion Devices

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

## Indications for Use

510(k) Number (if known)  
K252130

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.

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### 510(k) Summary

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

<b>Submitter Information</b>	
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 26, 2026
<b>Name of device</b>	
Trade or proprietary name	LifeShield™ Infusion Safety Software Suite
Common or usual name	Infusion Safety Management Software
Classification	Class II
Classification Reason	21 CFR 880.5725
Panel	General Hospital
<b>Product Code(s)</b>	PHC
<b>Predicate Device</b>	K242117, LifeShield™ Infusion Safety Software Suite
<b>Reason for 510(k) submission</b>	The submission is a traditional pre-market notification for software modifications made to LifeShield™ Infusion Safety Software Suite.
<b>Device description</b>	<p>The LifeShield™ Infusion Safety Software Suite is a cloud-based platform provided as a software-as-a-service (SaaS) and is hosted by Amazon Web Services (AWS). LifeShield™ Infusion Safety Software Suite is designed to be compatible with ICU Medical large volumetric pumps (Plum Duo™ Precision IV infusion pump, Plum Solo™ Precision IV infusion pump).</p> <p>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.</p> <p>The LifeShield™ Drug Library Management (DLM) software is used by pharmacists to create approved drug libraries that can be downloaded by the</p>

	<p>compatible infusion pumps. The latest software version implements general workflow enhancements.</p> <p>The LifeShield™ Clinical Dashboards &amp; 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 displays infusion and device information including reporting of pump location from the third-party location system.</p> <p>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 and alarms to the HIS. The latest software version allows connectivity with third-party location systems.</p>
<p><b>Intended Use of Device/Indication for use</b></p>	<p>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 adults, pediatrics and neonates undergoing infusion therapy with connected compatible infusion pumps (as per the indications for use specified for the compatible infusion pump).</p> <p>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.</p> <p>The LifeShield™ Clinical Dashboards &amp; 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.</p> <p>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</p>

	<p>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.</p>
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Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	Subject Device	Predicate K242117	Comparison
<b>Indications for Use</b>	<p>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).</p> <p>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.</p> <p>The LifeShield™ Clinical Dashboards &amp; 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 decision or treatment pathways.</p> <p>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</p>		Same

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	Subject Device	Predicate K242117	Comparison
	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.		
<b>Prescription Device</b>	Yes		Same
<b>Stand-alone software or embedded software</b>	Stand-alone		Same
<b>Application Type</b>	Web-based		Same
<b>Compatible Browser</b>	Google Chrome, Microsoft Edge		Same
<b>Database provider</b>	Amazon Web Services Cloud		Same
<b>Compatible Infusion Pump</b>	Plum Duo Plum Solo	Plum Duo Plum Solo	Same
<b>Drug library Capacity</b>	40 Clinical Care Areas / 40,000 total rulesets		Same
<b>No Drug Selected</b>	Available for all drug libraries		Same
<b>Drug Library Report</b>	Single printable report		Same
<b>Facility support</b>	Multiple facilities for drug library and data reporting		Same
<b>Available Drug Library</b>	Plum LVP (Plum Duo™, Plum Solo™)	Plum LVP (Plum Duo™, Plum Solo™)	Same
<b>Drug Library Workflow</b>	-Enhanced copy ruleset feature -Drug library content review and approval	-Ability to copy existing ruleset -Drug library content review and approval	Similar  Updates included workflow and user interface refinements to better

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	Subject Device	Predicate K242117	Comparison
	-UI improvements for managing a larger number of drug library and pump software updates	-Ability to view status of drug library and pump software updates.	facilitate creating and scheduling updates of drug libraries. Identified risks are effectively mitigated, confirming the changes did not raise different questions of safety and effectiveness.
<b>Drug Library Settings</b>	Plum LVP (Plum Duo™, Plum Solo™) settings		Same
<b>Infusion and Device Status Display</b>	Near-real time		Same
<b>Historical Reports</b>	Historical reports can be configured for the customer account and are displayed for drug library management, infusion data management and asset management.		Same
<b>Auto-programming</b>	Supported		Same
<b>Alarm Forwarding</b>	Supported		Same
<b>Infusion Documentation</b>	Supported		Same
<b>Asset Management</b>	-Drug Library Update -Software Update of Pump -Device status view with customizable access point description or with locations service data -Display of Pump Certificate Status -Pump Log Download	-Drug Library Update -Software Update of Pumps -Device status view with customizable access point description -Display of Pump Certificate Status -Pump Log Download	Similar  Both subject and predicate devices offer the same set of features to manage the pump fleet, with the subject device introducing the ability to archive pumps to help streamline the list of pumps to be managed and reporting pump locations from third-party location systems. Minor improvement to display of device

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	Subject Device	Predicate K242117	Comparison
			status does not raise different questions of safety and effectiveness.
<b>Multi-factor Authentication</b>	Time-based one-time password with ability to enforce for all users.	Time-based one-time password	Similar  The subject device adds an additional layer of security by providing the option to enforce multi-factor authentication on all users.
<b>Digitally-signed Drug Library</b>	Supported		Same

### **Summary of Non-Clinical Testing**

Non-clinical testing 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 effectiveness, and 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 studies demonstrate the effectiveness of the user interface design for additional features and their associated critical tasks. The human factors studies are conducted in accordance with 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 substantially equivalent to the currently marketed predicate device.