August 24, 2023

ICU Medical, Inc.
Pernell Abrantes
Senior Manager, Global Regulatory Affairs
600 N. Field Drive
Lake Forest, Illinois 60045

Re: K223606
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: July 24, 2023
Received: July 28, 2023

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 (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: Drug Delivery and General Hospital Devices & 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

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.

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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Section 5: 510(k) Summary

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 880.5725 for LifeShield™ Infusion Safety Software Suite.

Submitter Information	
Name	ICU Medical, Inc.
Address	600 North Field Drive Lake Forest, IL. 60045
Phone number	224-706-2229
Fax number	N/A
Establishment Registration Number	3013319212
Name of contact person	Pernell Abrantes
Date prepared	November 11, 2022
Name of device	
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
Product Code(s)	PHC
Legally marketed device(s) to which equivalence is claimed	Hospira MedNet™ Medication Management Suite cleared under K141102
Reason for 510(k) submission	The submission is a traditional pre-market notification for a new device 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™ 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 product is used by pharmacists to create approved drug libraries that can be downloaded by the infusion pumps. Drug libraries contain information on medications along with rulesets and associated clinical care areas (CCA) defined by pharmacists in accordance to their facility's best practices. Certain infusion pump parameters are also defined in the drug library. The LifeShield™ Device Manager (DM) and LifeShield™ Data Flow Management (DFM) are used to make the drug libraries available for the infusion pump to download and install. Download and installation of a drug library to the infusion pump establishes alert parameters for a medication that is being programmed for infusion. Additionally, the infusion pump applies the user-defined drug library settings for the configurable features of the pump. The LifeShield™ Clinical Dashboards & Reports (CDR) software is used by clinical administrators to view infusion or device-related information received from the Plum Duo™ infusion pump via the LifeShield™ DFM. It provides a near real-time view of ongoing infusions and their status; a view of all infusion pumps with their asset information and operational status; dashboards that provides easy navigation of key infusion or asset metrics; and an analytics viewer that users can use to view historical infusion and/or asset information. 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. The information presented by the software does not create decisions or treatment pathways for patients. LifeShield™ CDR is able to display infusion and infusion pump information from a single or multiple facilities within the customer account. LifeShield™ Infusion Safety Software Suite can be configured to interface with a facility's Hospital Information System (HIS) / EHR system to support auto-programming and infusion documentation. When the auto-programming feature license is enabled, the LifeShield™ Infusion Safety Software Suite can receive a pharmacy-validated order (also referred as auto-program order) from the HIS/EHR and route it to the infusion pump where the therapy program is pre-populated with physician-prescribed medication and infusion parameters, helping to reduce manual entry by the clinician when programming the pump. LifeShield™ Infusion Safety Software Suite does not modify the contents of the auto-program order received from the HIS/EHR. When the infusion documentation feature license is enabled, the LifeShield™ Infusion Safety Software Suite forwards the infusion data it receives from the infusion pump to the HIS/EHR system to support the

	facility's documentation of infusion information and HIS/EHR dashboards. Infusion data includes infusion status (e.g. volume change) and events (e.g. infusion start, stop, complete). LifeShield™ Infusion Safety Software Suite does not modify the contents of the infusion data sent to the HIS/EHR.
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 adults, pediatrics and neonates 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.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K141102**	**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 adults, pediatrics and neonates 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	The Hospira MedNet™ Medication Management Suite (MMS) is intended to facilitate networked communication between MMS compatible computer systems and Hospira Infusion pumps. The MMS provides trained healthcare professionals with the capability to send, receive, report, and store information from interfaced external systems, and to configure and edit infusion programming parameters. The MMS is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data. All data entry and validation of infusion parameters is performed by a trained healthcare professional according to physician's orders.	Similar Subject device indications statement includes clarifying details on the device purpose. 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 K141102**	**Comparison**
	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.		
Prescription Device	Yes		Same
Stand-alone software or embedded software	Stand-alone		Same
Application Type	Web-based	Web-based for server software PC-based Application (drug library)	Similar This does not raise different questions of safety and effectiveness as users require valid credentials to access and use the devices.
Database	Amazon Web Services Cloud	Local Server	Different

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K141102**	**Comparison**
provider			The use of the cloud allows the subject device to manage larger datasets and maintain system availability in support of the device's intended use. This does not raise different questions of safety and effectiveness.
Compatible Infusion Pump	Plum Duo (FRN, large volume infusion pump)	Plum 360: (FRN, large volume infusion pump)	Similar Both subject and predicate devices support large volume infusion pumps to provide drug libraries, transmit auto-program orders, and process infusion information. This does not raise different questions of safety and effectiveness.
Drug library Capacity	40 Clinical Care Areas / 40,000 total rulesets	40 Clinical Care Areas / 16,000 total rulesets	Similar The subject device expands its capacity to support larger numbers of medication rulesets within a single drug library. 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 K141102**	**Comparison**
No Drug Selected	Available with program and delivery mode settings	Available with no settings	Similar The subject device adds settings for "no drug selected" rulesets to provide an additional level of protection when this option is selected during programming. This does not raise different questions of safety and effectiveness.
Drug Library List	Available with dashboard	Available with no dashboard	Similar The addition of the dashboard in the subject device provides a convenient way for users to access drug libraries in the system. This does not raise different questions of safety and effectiveness.
Drug Library Report	Single printable report	Multiple printable reports	Similar Consolidation of drug library data in a single report by the subject device 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 K141102**	**Comparison**
Facility support	Multiple facilities for drug library and data reporting	Single facility for drug library and data reporting	Similar The subject device enhances predicate functionality by allowing deployment of a drug library to multiple facilities, as well as processing infusion data from multiple facilities. This does not raise different questions of safety and effectiveness.
Drug Library Settings	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	General Pump Settings for Plum 360™ Program Delivery Mode CCA settings for Patient weight, height and BSA Concentration Type Therapy-based medication limits Clinical Use	Similar The subject device enhances existing drug library settings by aligning with configurable pump features, adding additional limits, clinical advisory, and a way for users to flag medications that are high-alert. This does not raise different questions of safety and effectiveness.
Therapy mode Settings	Continuous, Bolus, Loading Dose, Multistep	Continuous	Similar The subject device enhances the drug library by supporting additional therapy mode settings, allowing users to provide

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K141102**	**Comparison**
			additional rules for those modes. This does not raise different questions of safety and effectiveness.
Medication Unit Family	grams, mL, Units, mmol, mEq		Same
Number of medication units	119	98	Similar The subject device adds medication units to provide a wider range of units that can be selected when creating a drug library. This does not raise different questions of safety and effectiveness.
Infusion and Device Status Display	Near-real time		Same
Infusion Status Information	Displays details of infusions active within 1 hr with added information pertaining to the infusion	Displays details of infusions active within 1 hr	Similar The subject device provides additional information associated with the displayed ongoing infusions. The added information does not affect the purpose of the near real-time display. This does

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K141102**	**Comparison**
			not raise different questions of safety and effectiveness.
Historical Reports	Reports imported from external tool. Report availability is configurable	Reports generated from built-in report templates. Report availability not configurable	Similar The subject device allows flexibility in what historical reports are made available to the account in accordance with the customer needs. This does not raise different questions of safety and effectiveness.
Auto-programming	Routes digitally-signed pharmacy-validated orders from the HIS/EHR system to the pump	Routes pharmacy-validated orders from the HIS/EHR system to the pump	Similar The subject device improves this feature by digitally signing the auto program order to ensure integrity of the order is maintained when received by the pump. The difference does not affect the purpose of the auto-programming feature. This does not raise different questions of safety and effectiveness.
Infusion Documentation	Routes infusion data with added details on wireless connectivity to the HIS/EHR system to support documentation	Routes infusion data to the HIS/EHR system to support documentation	Similar The subject device provides

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Subject Device**	**Predicate K141102**	**Comparison**
			additional information in the infusion data that is sent to the HIS/EHR. The added information does not affect the purpose of the infusion documentation feature. This does not raise different questions of safety and effectiveness.
Asset Management	Supports Drug Library Update Supports Pump Software Update Display of Device Status		Same
User access	Requires login for system access (with additional password requirements) Requires Role-base access	Requires login for system access Requires Role-base access	Similar The subject device enhances system security by requiring users to use stronger passwords. This does not raise different questions of safety and effectiveness.
Multi-factor Authentication	Yes	No	Different The subject device provides an additional layer of security to access the device. 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 K141102**	**Comparison**
Digitally-signed Drug Library	Yes	No	Different The subject device employs digital signing of drug libraries, ensuring the integrity of the drug libraries files. This does not raise different questions of safety and effectiveness.

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 the overall safety and effectiveness of the subject device, supporting a substantial equivalence determination of LifeShield Infusion Safety Software Suite to the predicate device Hospira MedNet™ Medication Management Suite. A summary of the testing conducted is presented below.

- Design verification tests passed established acceptance criteria, confirming the subject device meets design requirements. Verification activities also included software verification, performance, reliability, compatibility tests, and systems integration tests with the compatible infusion pump. Software verification followed the software development process outlined in IEC 62304:2015.
- Cybersecurity evaluation and testing demonstrate that the software is reasonably secure.
- Design validation tests passed established acceptance criteria, confirming the subject device meets all intended users' needs.
- Risk management activities are performed in accordance to 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.
- Human Factors studies demonstrate the effectiveness of the user interface design for key features and their associated critical tasks. Human Factors studies were conducted in accordance to IEC 62366-1:2015 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 LifeShield™ Infusion Safety Software Suite is as safe and effective for its intended use as the currently marketed predicate device Hospira MedNet™ Medication Management Suite. Verification, validation, cybersecurity and human factors testing conducted demonstrate that LifeShield™ Infusion Safety Software Suite meet all acceptance criteria requirements, and confirm that no different questions and safety and effectiveness are raised. Therefore, the subject device – LifeShield™ Infusion Safety Software Suite is substantially equivalent to the currently marketed predicate device – Hospira MedNet™ Medication Management Suite.