ICU Medical Introduces Its New Category of Infusion Devices With FDA Clearances of Plum Solo™ and Plum Duo™ Precision IV Pumps

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New devices address infusion delivery variability and expand the ICU Medical IV Performance Platform.

SAN CLEMENTE, Calif., April 7, 2025 /PRNewswire/ -- ICU Medical Inc. (NASDAQ:ICUI), a worldwide leader in the development, manufacture and sale of innovative medical devices, has announced 510(k) regulatory clearance from the U.S. Food and Drug Administration (FDA) for the Plum Solo™ precision IV pump, a single-channel complement to the dual-channel Plum Duo™. ICU Medical also received 510(k) clearance for updated versions of the Plum Duo precision IV pump and LifeShield™ infusion safety software, completing the initial launch of the ICU Medical IV Performance Platform. With these FDA clearances, ICU Medical is introducing its new category of precision IV pumps and expanding the ICU Medical IV Performance Platform.

Unlike traditional pumps that rely on specific setups and conditions for accurate delivery, precision IV pumps are designed to address delivery variability while supporting the increasing need for accurate data in modern patient care. Built on the unique cassette technology in the Best in KLAS award-winning Plum 360™, the Plum Solo and Plum Duo precision IV pumps deliver ±3% accuracy in real-world conditions and eliminate the infusion inconsistencies found in traditional pumps, providing clinicians with predictable performance and reliable infusion documentation.

"Precision IV pumps represent a critical step forward for infusion therapy," said Chad Jansen, corporate vice president and general manager of ICU Medical Infusion Systems. "With the Plum Solo and Plum Duo, we're introducing more than just a new device category—we're setting a new standard. Healthcare teams can now trust not only the delivery of their medications but also the infusion data that supports their decisions, knowing it reflects what patients actually receive."

The Plum Solo expands the capabilities of the IV Performance Platform by offering a single-channel pump designed to work alongside the dual-channel Plum Duo—recently recognized in a KLAS Emerging Insights Report with emerging data showing an A+ rating for new technology, likely to recommend, and money's worth.

Together, Plum Solo and Plum Duo provide healthcare systems with the flexibility to choose the right configuration for their infusion needs, optimizing device footprint without compromising performance or safety. Both devices are compatible with whole blood and blood products and deliver consistent ±3% accuracy while eliminating variability from external factors such as infusion setup, temperature, or hospital elevation. Benefits of the IV Performance Platform include:

- **Precise Delivery:** Unique pumping mechanism allowing for accurate and precise medication delivery—including whole blood and blood products—with both Plum Solo and Plum Duo pumps, no matter where the pump or the infusion bag is placed.
- **Simplified User Experience:** Full-color touchscreens (7-inch on Plum Solo, 10-inch on Plum Duo) deliver intuitive programming with near real-time safety feedback for faster workflows and reduced cognitive load.
- **Streamlined Medication Management:** Simplified drug library and firmware deployment, managed from a central location anytime, anywhere, to help ensure devices are consistently updated and pumps are on the most current software version.
- **Full IV-EHR Interoperability:** Built on ICU Medical's 16 years of industry-leading experience, LifeShield software connectivity and integration can support better decision-making and more coordinated care across healthcare systems.
- **Future Ready:** The LifeShield enterprise ecosystem will provide a single, harmonized IT platform for ICU Medical's road

map of delivering best-of-breed devices for every infusion modality.

"We are proud of this milestone, but this is just the next step in creating the most comprehensive, precise, and technologically advanced infusion platform," Jansen said. "This milestone delivers on our promised roadmap with 5 products receiving FDA 510(k) clearance in the past 18 months. We look forward to bringing our next-generation Medfusion™ syringe pump and CADD™ pain and ambulatory pump products to the LifeShield platform. This is the future of infusion therapy, and we're proud to be leading the way."

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