

## Tandem receives FDA approval for t:slim X2 Insulin Pump

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Tandem Diabetes Care has announced the U.S. Food and Drug Administration (FDA) approval of its t:slim X2™ insulin pump.

Along with this authorization, the FDA is establishing criteria, called special controls, which outline requirements for assuring the accuracy, reliability, cybersecurity and clinical relevance of ACE pumps, as well as describe the type of studies and data required to demonstrate acceptable pump performance. The approved indication for the t:slim X2 pump states that the pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

Kim Blickenstaff, president and CEO of Tandem Diabetes Care said, "This new classification of the t:slim X2 pump provides more flexibility for us as we make improvements to current products, create new products, and collaborate with best-in-class companies in the development of future automated insulin delivery systems. This further establishes the role Tandem Diabetes Care has taken as a key innovator in the insulin pump industry, having launched the first touchscreen pump in the United States, the first pump capable of remote feature updates, the first pump approved as iCGM compatible, and now the first in this new interoperable pump category."

John Sheridan, executive vice president and COO of Tandem Diabetes Care said, "The FDA's special controls set a new standard in our industry and define another component of the regulatory process for future automated insulin delivery systems. Having the t:slim X2 pump approved with this new designation, combined with its ability for remote software updates, will enable more efficient and predictable development of new systems with current and future technology partners, and allow faster delivery of new innovations to our customers."

t:slim X2 insulin pump includes features like a large color touchscreen, rechargeable battery, Bluetooth® wireless technology, USB connectivity and watertight construction (IPX7). It is capable of remote software updates using a personal computer, offering the potential for users to access new features as they meet necessary regulatory requirements. The t:slim X2 Pump is up to 38 percent smaller than other insulin pumps and holds up to 300 units of insulin.