

First customizable insulin pump approved

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(HealthDay)—The Tandem Diabetes Care t-Slim X2 insulin pump, which allows a patient to customize treatment, has been approved by the U.S. Food and Drug Administration.

"Diabetes is a complicated disease that requires close monitoring and

carefully tailored treatments. We've heard from the patient community that having the ability to customize their own diabetes management devices is important to them," FDA Commissioner Dr. Scott Gottlieb said in an agency news release. "Advances in digital health make more tailored approaches to [diabetes care](#) possible."

The new device is described as either an alternate controller enabled (ACE) [infusion pump](#) or an interoperable pump, so it can be used with different components that allow users to tailor diabetes management to their preferences, according to the agency.

Nearly 10 percent of Americans have been diagnosed with diabetes, which hinders the body's ability to make or properly use the [blood sugar](#) -regulating hormone insulin.

The product works by delivering insulin under the skin at set or variable rates. It can be digitally connected to automatically communicate with and receive drug-dosing commands from other diabetes-management devices, the FDA said.

Along with this approval, the FDA said it is establishing "special controls" that define requirements for assuring the accuracy, reliability and cybersecurity of ACE infusion pumps. These controls also describe the type of studies and data required to demonstrate acceptable performance.

Potential side effects of the newly approved device include infection, bleeding, pain, [skin irritation](#), blockages and air bubbles in the tubing, the agency said.

The product is made by Tandem Diabetes Care, based in San Diego.

More information: Visit the [American Diabetes Association](#) for more

on insulin pump systems.

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