

## FDA approves first automatic insulin dosing system

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The U.S. Food and Drug Administration has authorized marketing of the Tandem Diabetes Care Control-IQ Technology, an interoperable automated glycemic controller device that automatically adjusts insulin delivery to a person with diabetes by connecting to an alternate controller-enabled insulin pump (ACE pump) and integrated continuous glucose monitor (iCGM).

This is the first such controller that can be used with other diabetes devices that are also designed to be integrated into a customizable diabetes management system for automated insulin delivery. This FDA authorization paves the way for iCGMs and ACE pumps to be used with an interoperable automated glycemic controller as a complete automated insulin dosing (AID) system. AID systems typically consist of a pump, CGM and software to control the system of compatible devices.

Tim Stenzel, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health said, "Today's action continues the agency's ongoing efforts to work with the diabetes community to help ensure the safety and efficacy of innovative and customizable diabetes management systems that may help patients better tailor their treatments to their individual needs. The marketing authorization of this first stand-alone interoperable automated glycemic controller also allows substantially equivalent controller technologies that are developed for diabetes in the future to go through the 510(k) review process, helping to promote timely patient access to innovative technologies that can improve their care and quality of life."

Diabetes impairs the body's ability to make or properly use the blood glucose-regulating hormone insulin and impacts nearly 10% of Americans. In type 1 diabetes, once known as juvenile diabetes, the patient's pancreas produces little or no insulin. Five percent of patients with diabetes have type 1 diabetes.

The Control-IQ Technology controller is a new type of glycemic controller that when used as a system with compatible iCGMs and ACE pumps can be used by patients with type 1 diabetes to automatically increase, decrease and suspend delivery of basal insulin to the patient based on insulin delivery history, iCGM readings and predicted glucose values. The controller can also automatically deliver a specific amount of insulin when the glucose value is predicted to exceed a predefined amount. Other software to automatically control insulin delivery has previously been approved by the FDA as part of a single,

predefined diabetes management system (as a class III, high-risk device).

The FDA granted marketing authorization of the Control-IQ Technology controller to Tandem Diabetes Care Inc.