

First fully interoperable automated insulin dosing device: From DIY to FDA clearance



About Tidepool

[Tidepool](#) is a 501c(3) nonprofit organization committed to helping individuals with insulin-dependent diabetes through accessible, actionable, and meaningful data. Tidepool Loop is the first fully interoperable automated insulin dosing app cleared by the FDA, and it originated as a patient-led innovation. ([Tidepool+ Data Platform](#), [Tidepool Loop](#))



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The opportunity

- Dissatisfied with market diabetes tech, many turned to [creating DIY devices](#), raising [safety concerns](#).
- Tidepool was keen to create a **regulated version of the unregulated DIY app**, enabling easier access for diabetes patients and healthcare providers without the need to build it themselves.



The challenge

- Tidepool Loop is a closed-loop automated insulin delivery system that controls insulin delivery, impacting patient safety and **requiring FDA regulation**.
- In 2015, the FDA anticipated an impending wave of closed-loop automated insulin delivery (AID) systems. However, reviewing AIDs as a unified system, where each update to any component necessitates a comprehensive system review, made the process slow and untenable.



The approach

- Tidepool discussed a **potential expedited pathway** for interoperable AID system components with the FDA, allowing the components of an AID system to be reviewed independently. **This streamlined the process for Tidepool and the FDA**, even with [existing nuances of the interoperability pathway](#), while providing greater choice to the diabetes community.
- **The FDA has created new regulatory pathways** for three types of components, allowing new De Novo authorization to [Dexcom for the G6 as an iCGM](#) in 2018 and in 2019 to [Tandem for T: Slim X2 ACE Pump and Control IQ Technology Interoperable Automated Glycemic Controller](#) (IAGC).
- Such **early engagement with the FDA** streamlined Tidepool's pathway to 510(k) regulatory clearance, identifying optimal requirements for a device design that is fully interoperable with both third-party ICGM devices (like the Dexcom G6) and third-party ACE Pumps.



The success

- ✓ **Collaboration is a pivotal step** towards a world where people with T1D and their healthcare providers can choose the best pump, CGM, and algorithm for them, with all three working together.
- ✓ Tidepool Loop is a predicate device for future fully interoperable AID submissions, **providing a more clearly defined pathway through the regulatory process** and bringing new, novel diabetes solutions to the market.



We have taken the foundation built by our friends in the open-source diabetes community who believe management tools should work better together and built a system we are proud of. We're committed to **working alongside the FDA and our device partners** to drive device interoperability and market access progress."

— **Howard Look**

CEO and co-founder, Tidepool