

Tidepool's Regulatory Journey

For an automated insulin dosing app intended for the management of type 1 diabetes

The Story

On January 11, 1922—over 100 years ago—a 14-year-old boy with diabetes named Leonard Thompson received the very first injection of insulin. As a father of a child with diabetes, [Tidepool](#) CEO and co-founder, Howard Look, is well aware of the impact of this discovery. And while he is in awe of how far diabetes management has come over the past century, he is also aware of how much more can be done. Inspired by the #WeAreNotWaiting community of innovators, this motivated him and the rest of his team to develop Tidepool Loop: the first fully interoperable automated insulin dosing app with the goal of making it widely available in the App Store.

The Product | FDA cleared

FDA Regulatory Pathway: 510(k) pathway ([K203689](#))

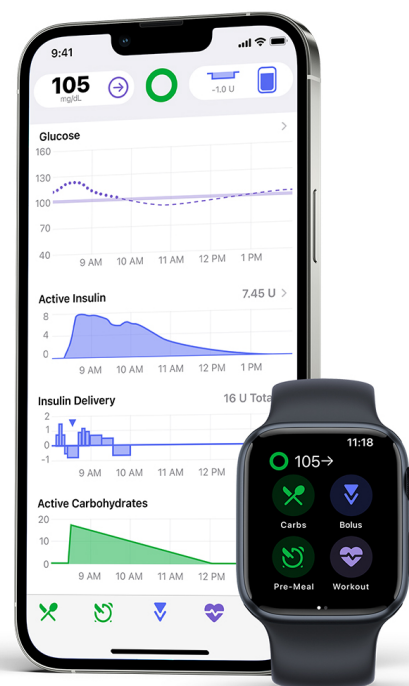
Name: Tidepool Loop

Intended use/Indication of use: Tidepool Loop, a mobile application with algorithm technology, is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) insulin infusion pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend, and with the user's confirmation, control the delivery of correction boluses when glucose values are predicted to exceed user configurable thresholds. Tidepool Loop is intended for the management of type 1 diabetes mellitus in persons six years of age and greater. Tidepool Loop is intended for single patient use. Tidepool Loop is Rx - For Prescription Use Only

FDA class: Class II Medical Device

Product code: QJI

Regulation section: 21 CFR 862.1356 - Interoperable Automated Glycemic Controller



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The Value | Regulated vs non-regulated

Tidepool Loop is a closed loop automated insulin delivery system which **needs to be regulated as it controls the delivery of insulin that impacts patient safety**. Tidepool chose to create a regulated version of an existing DIY effort in the community so that people with diabetes and their healthcare providers could have access to an easily accessible FDA regulated version of this app without needing to know how to build it themselves.

The Strategy | Fit-for-purpose

In 2015, the FDA knew that there was an impending **wave of closed-loop automated insulin delivery (AID) systems**. But reviewing AIDs as a system (reviewing *together* each time any component was updated), where the submission would need to include everything about the system, was going to be slow and untenable. Therefore, FDA spoke to organizations like [JDRF](#) and Tidepool about their desire to make an expedited pathway for interoperable AID system components: **allowing the components of an AID system to be reviewed independently**. This made things easier for both industry and the FDA, while providing greater choice to the diabetes community; even with [existing nuances with the interoperability pathway](#).

The FDA has created new pathways for components (and the companies that make them) to work together so that users might one day have more choices in the systems they use. They've determined 3 types of components and a regulatory pathway for each:



ACE Pump

“alternate controller-enabled pump”

What that means: the pump is designed to be able to work safely with more than one type of algorithm that adjusts insulin



iCGM

“integrated continuous glucose monitor”

What that means: the CGM system meets FDA’s criteria for accuracy and safety for dosing insulin



iAGC

“interoperable automated glycemic controller”

What that means: The algorithm (computing logic) has been designed to communicate with other compatible diabetes device components in a modular system.

The Influencing Factors | Building it right

By early 2018, **FDA began rolling out their interoperability pathway** via de novo for all 3 types of components. In 2018, Tidepool also announced the **launch of the Tidepool Loop development** efforts, a project dedicated to delivering an FDA regulated version of the unregulated DIY Loop app, making it broadly available to download via the iOS App Store. The goal was to be the first to champion true interoperability with an **app that would work with compatible ACE pumps and iCGMs**, made by different manufacturers, that were cleared to work with automated insulin dosing systems.



In 2018, FDA issued de novo authorization to [Dexcom for the G6 as an iCGM](#), and in 2019 to [Tandem for T: Slim X2 ACE Pump](#) and [Control IQ Technology iAGC](#). These de novo submissions paved the way for all following submissions for the same kind of devices from other companies as Class-II devices.

In order to meet their goal of making Tidepool Loop widely available in the App Store, Tidepool **submitted an application to the FDA for 510(k) clearance** in December 2020.

The next great leap forward in diabetes is automation. With Tidepool Loop, this fully interoperable iAGC device's design enables interoperability with both third party iCGM devices (like the Dexcom G6) and third party ACE Pumps.. **These plans mean that over time, Tidepool can continue to add compatibility with new iCGM devices and new ACE Pump devices to Tidepool Loop, and that no new FDA filing is required!**

The Impact | Value in ripple effects

Tidepool Loop is the **first fully interoperable automated insulin dosing app**, cleared by the FDA, that originated as a patient-led initiative.

The FDA clearance is a pivotal step towards a world where people with T1D can choose the pump, CGM, and algorithm that are best for them – and have all three work together. This makes an enormous **difference in how** the market, both **people with diabetes and healthcare providers perceive the app**. It also empowers the next generation of innovations in diabetes management as now, **Tidepool Loop can serve as a predicate device** for future interoperable Automated Insulin Dosing (AID) submissions - **providing a more clearly defined pathway** through the regulatory process.

Tidepool helped bridge the gap between the fast pace of innovation in the community and the rigor of current quality management systems. This is a triumph for stakeholders across the diabetes industry and, most importantly, will make a real impact in the lives of people with diabetes.

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 agency and our device partners to drive progress in the areas of device interoperability and access.

- **Howard Look**, CEO and co-founder, Tidepool

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Identify your regulatory pathway



Build your regulatory strategy



Interact with regulators

