## Digital Health Industry Regulatory Case Study

# TIDEPOOL

First fully interoperable automated insulin dosing

device: From DIY to FDA clearance

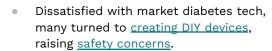


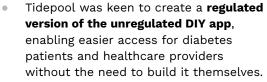
### **About Tidepool**

<u>Tidepool</u> 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. (<u>Tidepool+ Data Platform</u>, <u>Tidepool Loop</u>)



#### The opportunity







### 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 <a href="Dexcom for the G6">Dexcom for the G6 as an iCGM</a> in 2018 and in 2019 to <a href="Tandem for T:Slim X2">Tandem for T:Slim X2 ACE Pump</a> and <a href="Control IO Technology Interoperable Automated Glycemic Controller">Controller</a> (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

