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# From Pull Request to Patient Safety

How Tidepool Built an Open-Source  
Quality Management System

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TIDEPOOL



# Over 2 million Americans live with Type 1 diabetes

This open-source software decides how much insulin some of them get.



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# How Tidepool Loop Works



# Open Source. Cleared by FDA.

## Class II Software as Medical Device (SaMD)

Most people assume those two facts can't coexist



# Roadmap

- Who is Tidepool?
- Brief History of Tidepool Loop
- What Regulators Actually Require
- How We Built It
- Working with The Upstream
- Regulatory Release
- What Broke?
- Framework to Take Home



# Who is Tidepool?



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# This is Tidepool

Founded in 2013 by people with diabetes, caregivers, and leading healthcare providers, Tidepool is a 501(c)(3) nonprofit organization with a mission to make diabetes data more accessible, actionable, and meaningful. We do this by building open-source software and offering programs for both clinicians and people living with diabetes.

**970,000+**

Total lives touched, including  
people living with diabetes  
and clinicians

**90+**

Total supported devices

**3000+**

Total clinics

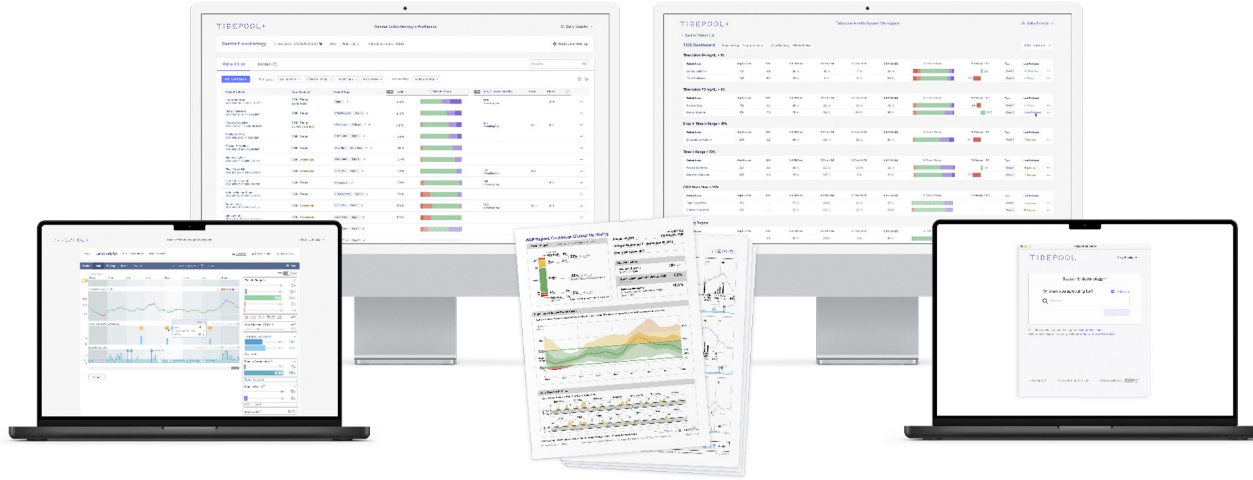
**26B+**

Data points collected

**12k+**

Registered healthcare  
providers

# Tidepool's Product Lines



## Tidepool+

Tidepool+ is an enterprise-ready diabetes data platform that connects devices, embeds insights in EHRs, and enables proactive, reimbursable care.



## Tidepool Loop

An automated insulin dosing application for people living with type 1 diabetes.

# Brief History of Tidepool Loop



# Before Tidepool Loop, There Was (DIY) Loop for iOS

## #WeAreNotWaiting

- Open-source automated insulin delivery (AID) app
- Built by and for the T1D community
- Patients and parents who got tired of waiting for industry
- Thousands of users.
- No FDA involvement. No formal QMS.

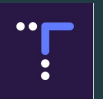


# From DIY Loop to FDA Clearance

- **2016:** DIY Loop (2016–present)
- **2018:** Tidepool decides to pursue FDA 510(k) clearance and forks DIY Loop
- DIY Loop Observational Study: 6 months, 558 people, ages 1-71
- **December 2020:** Submitted to FDA during a global pandemic
- **January 2023:** FDA clearance for Tidepool Loop

**The fork was open source from day one. It stayed open source through submission, through clearance, and is open source today.**

Lum JW, Bailey RJ, Barnes-Lomen V, et al. *Diabetes Technol Ther.* 2021;23(5):367–375.  
doi:10.1089/dia.2020.0535



# Tidepool Loop for Android = NEMO

- Funding announced May 2023
- Same QMS, same regulated discipline as Tidepool Loop for iOS
- Not yet open source. Not yet released.
- Cannot release until thoroughly tested, and cleared by FDA.

**The cost of shipping unsafe insulin-delivery software is measured in lives.**

Upcoming screenshots you'll see two ticket prefixes: LOOP for iOS, NEMO for Android.



# What Regulators Actually Require



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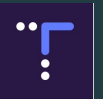
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# Four Things They Care About

- **Traceability**
  - Every requirement traces forward; every line of code traces back
- **Verification & Validation**
  - Documented evidence each requirement is met (V) and it is the right requirement (V)
- **Risk Management**
  - Identify hazards, mitigate them, prove the mitigations work
- **Change Control**
  - Every change reviewed, approved, and recorded for audits years later

IEC 62304 · ISO 13485 · ISO 14971



# Cross Domain Bridge

- **Medical devices:** IEC 62304 (software lifecycle)
- **Automotive:** ISO 26262 (functional safety)
- **Aviation:** DO-178C (airborne software)
- **Rail:** EN 50128
- **Industrial control:** IEC 61508

**Different details. Same skeleton: traceability, V&V, risk, change control.**



# Convention, Not Safety Requirement

**Nothing in any of these standards says you can't be open source.**

The standards describe what you must do, not how you do it.

The closed & proprietary is a convention, not a safety requirement.



# How We Built It



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# Document Control vs. Actual Tools

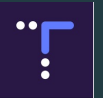
## What regulators expect

- A controlled document repository.
- Version numbers, signatures, effective dates, review cycles.
- Traditionally a six-figure enterprise QMS with an account executive.

## Our reality

- Google Docs, Figma, Jira, git.
- Each excellent at what it does.
- None designed to be a regulated document control system.

**The collision:** Make a heterogeneous best-of-breed toolchain behave like a single controlled-document system without a year of integration glue.



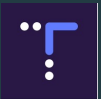
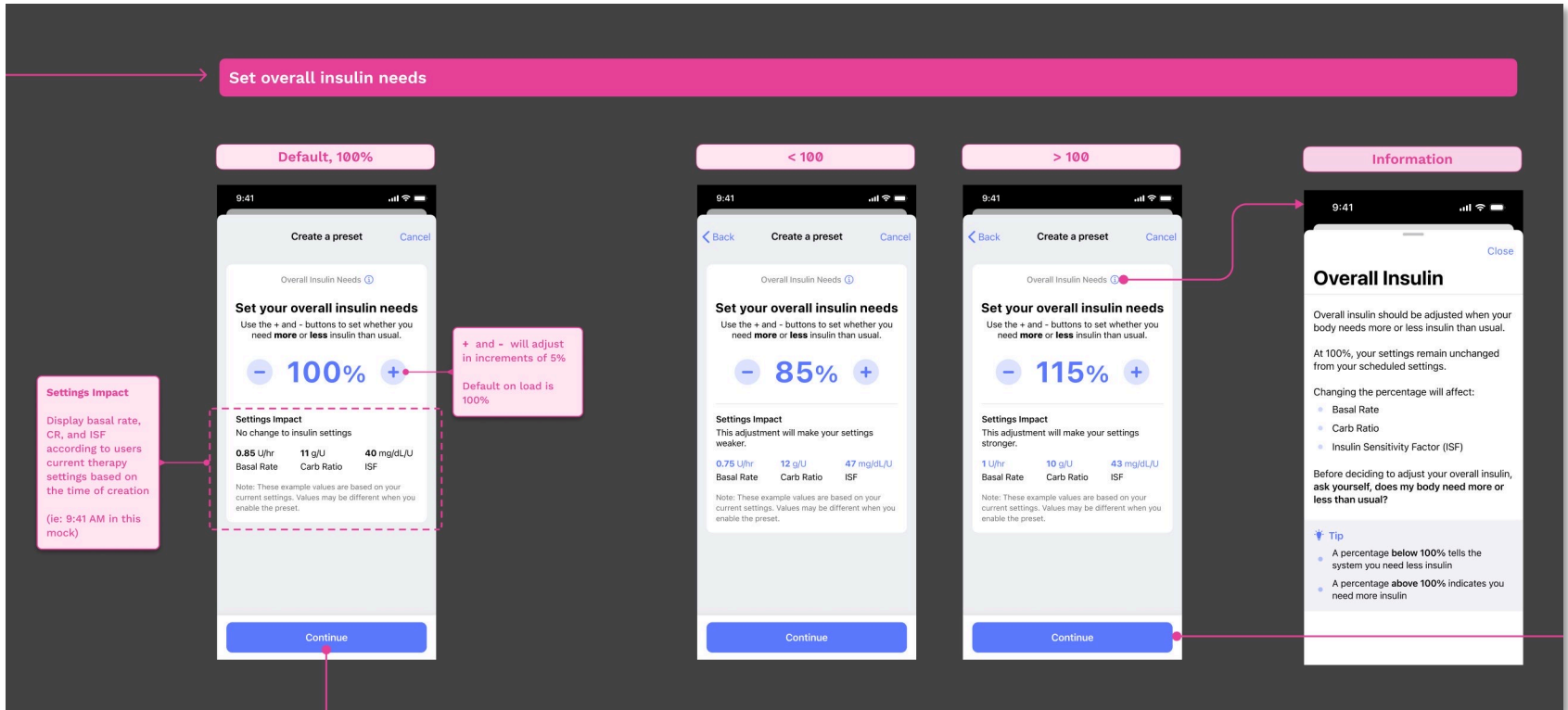
TLFR-645

# Presets Display

DIY Loop → Tidepool Loop v2.0



# Designing TLFR-645



# Where Requirements Live

Spaces / Tidepool Loop Functi... / TLFR-644 / TLFR-645

## Presets Display

+ @

Key details

Description

Tidepool Loop shall display information on the Presets Screen three main areas including:

- Currently Active Preset
- All Presets
- Support Related to Presets

From this screen, Tidepool Loop shall also allow users to view, manage, and enable/disable a given preset.

Linked work items

created

LOOP-5874 BUG: UI Anomaly: Correction Range Info screen button is 'Continue' instead of 'Cl... IN CODE REVIEW

defines

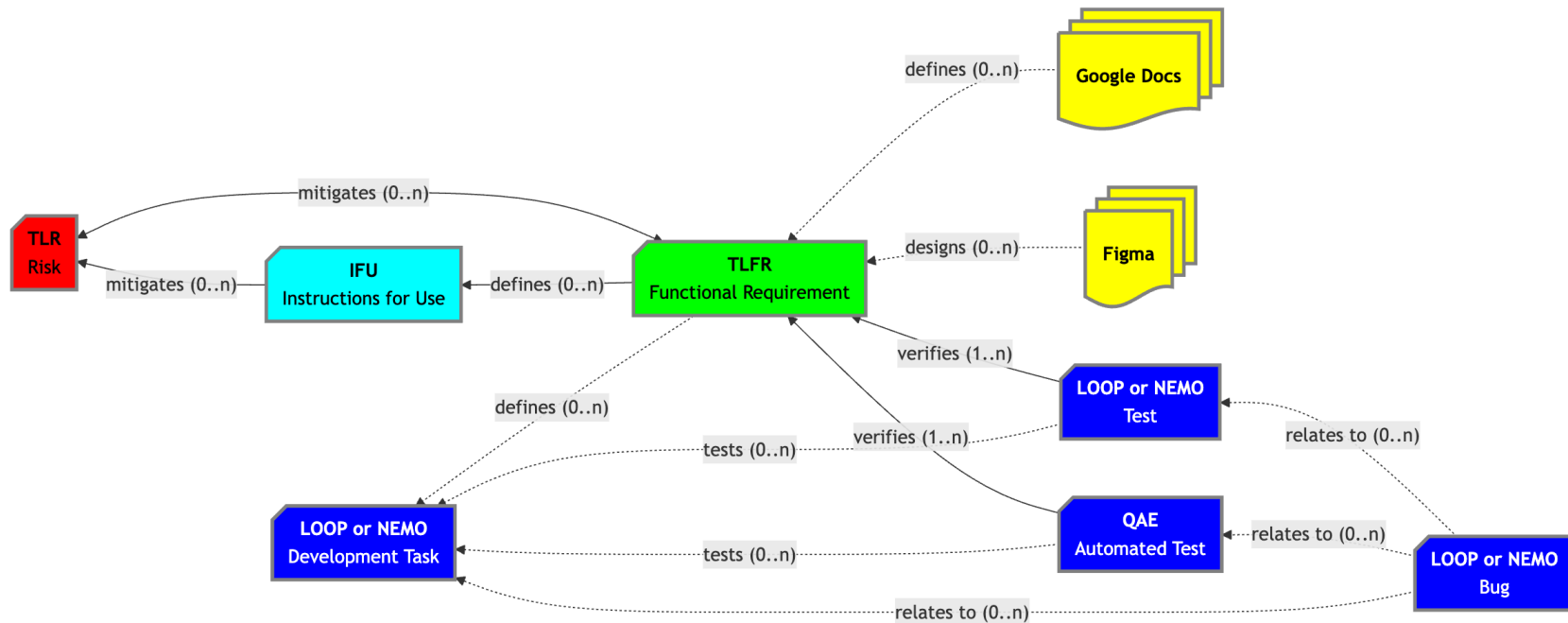
LOOP-5233 Creating a New Preset	CLOSED		
LOOP-5236 Preset Card States	CLOSED		
LOOP-5280 Preset Details Sheet	CLOSED		
NEMO-301 Preset Details Sheet	IN PROGRESS		
NEMO-302 Creating a New Preset	IN PROGRESS		
NEMO-305 Preset Card States	IN PROGRESS		

is tested by

LOOP-5185 Test Home Screen Loop 2.0 with Toolbar	PASSED		
LOOP-5324 Preset - Create New: indefinite duration to use at a later time	PASSED		
LOOP-5318 Preset: Create New - Scheduled Preset	PASSED		

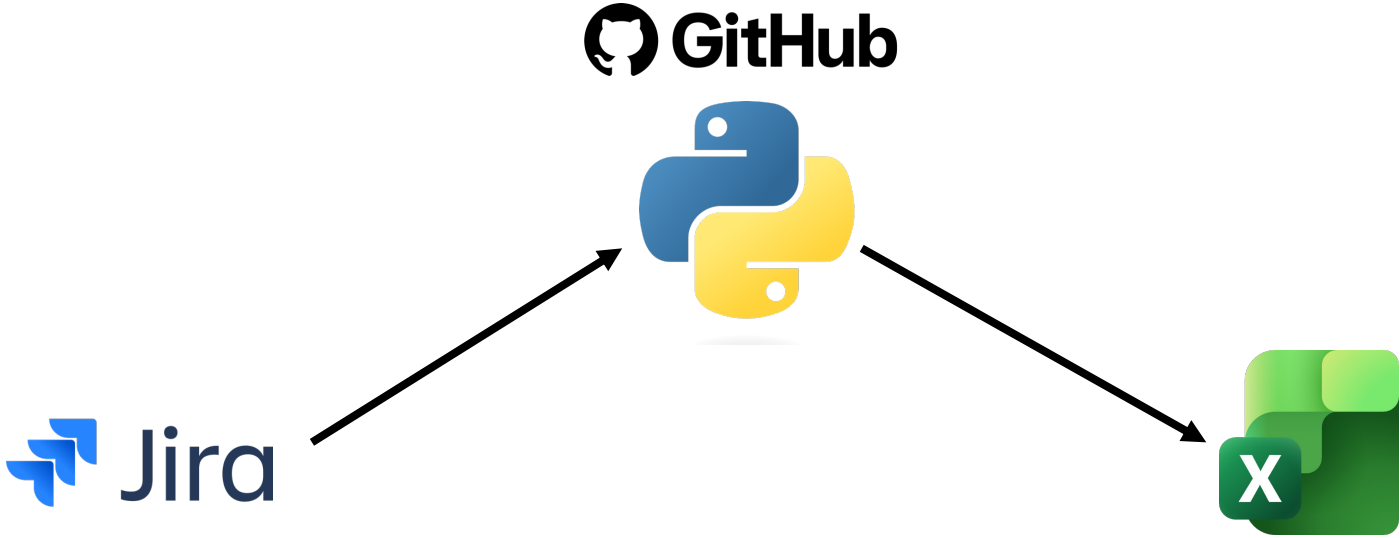


# Jira Constellation





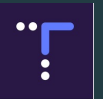
# Generated, Not Maintained



# Centralize The Mess

- Schema drift happens in any long-lived system. It is inevitable.
- **In the script:** rules are explicit, named, version-controlled, reviewable
- **In the workbook:** rules are tacit, scattered across rows and people, un-auditable

**Same total complexity. Very different reviewability.**



# Regulatory Triage

## Regulatory Change Checklist

### Instructions

#### DETAILS

This checklist must be completed prior to moving this ticket to Code Review. Anyone can complete it; contact Risk Management for assistance with the last question if necessary.

If *any* answer is YES, this ticket may proceed without further regulatory change assessment

If *all* answers are NO (indicated by **NOT**), a complete regulatory change assessment must be completed. Assign ticket to Risk Management.

*Do not use any other status indicators in the checklist.*

Prior to moving to **Waiting for Approval**, QA must review this checklist to ensure scope changes did not change any of this assessment.

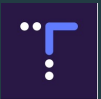
- A1.3: Is it a change to the device name or a labeling change solely to improve readability or clarity? NOT ▾
- S1: Is the change made solely to strengthen cybersecurity and does not have any other impact on the Tidepool Loop software? NOT ▾
- S2: Is the change made solely to return Tidepool Loop to the specification of the most recently cleared version? (This will cover most bug fixes) NOT ▾
- Is the change solely to improve readability, clarity, or user experience, **and** does not change existing risks or add new risks? NOT ▾



# Output from Risk Review

Spaces / Tidepool Loop Functi... / TLFR-644 / TLFR-645

LOOP-5546	Test Bug: Show Overall Insulin Guardrail state colors in Preset Screen Card State a...	PASSED ✓		<input type="radio"/>
LOOP-5698	Test Bug: User can restart an expired Single Use Preset through the details screen	PASSED ✓		<input type="radio"/>
<b>mitigates</b>				
TLR-1125	User changes therapy settings, intending it to be temporary, and forgets to change it ...	WAITING FOR API		<input type="radio"/>
TLR-1079	User does not understand that they can deactivate a Preset before the end of the co...	WAITING FOR API		<input type="radio"/>
TLR-892	User does not understand how Presets work	WAITING FOR API		<input type="radio"/>
TLR-1064	User unintentionally deletes a Preset	WAITING FOR API		<input type="radio"/>
TLR-1137	User does not understand that a preset has been disabled	WAITING FOR API		<input type="radio"/>
TLR-1147	Incorrect preset selection while in Closed Loop Off	WAITING FOR API		<input type="radio"/>
TLR-1112	User schedules a Preset for a specific time and accidentally confirms start: Phone	WAITING FOR API		<input type="radio"/>
TLR-1100	User does not understand what correction range is currently active	WAITING FOR API		<input type="radio"/>
TLR-1070	User unintentionally activates a Preset: Phone	WAITING FOR API		<input type="radio"/>
TLR-858	Accidental capacitive touch: user unintentionally activates the incorrect Preset	WAITING FOR API		<input type="radio"/>



# Working with The Upstream



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# Traceability Meets Upstream

## What regulators expect

- Formal requirements.
- Risk analysis & mitigation.
- An unbroken doc chain from requirements to git commits to verification tests.

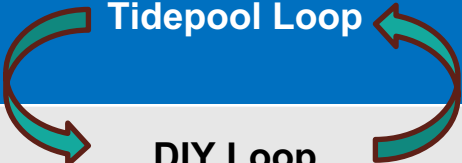
## Our reality

- There were no formal requirements.
- A thriving upstream still innovating
- We exchange code multiple times a year.

**The collision:** Stay close enough to absorb community innovation. Stay far enough to maintain regulatory traceability.



# A Third World

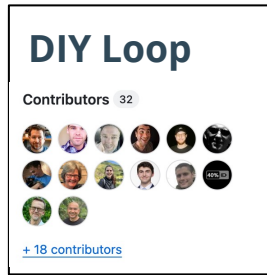
	Open Source	Closed Source
Regulated	 Tidepool Loop	Medtronic 780G Tandem Control-IQ Insulet Omnipod 5
Unregulated	DIY Loop OpenAPS AndroidAPS	



# DIY Loop and Tidepool Loop Today

- Multiple bidirectional merges per year, performed by a Tidepool engineer
- Some changes belong on one side only. Those become separable modules.

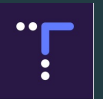
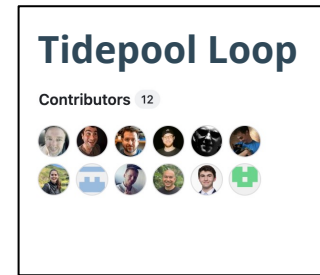
**Neither project is trying to replace the other.**



community experiments come over  
selectively, with regulatory wrapping



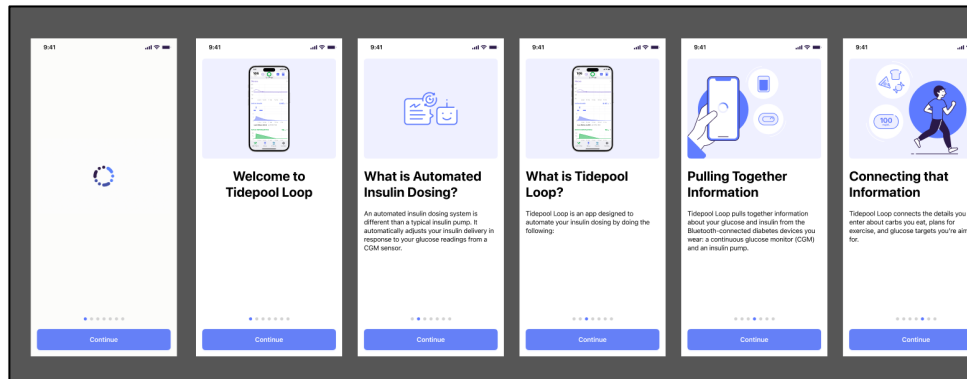
improvements offered back; not pushed



# Onboarding & Training

- Required for Tidepool Loop
- Too much for DIY Loop

➤ Isolate it in a separate repo

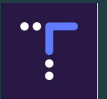


**Shared core stays shared. Differences live at clean architectural boundaries.**

# Here's How We Do It

The screenshot shows the GitHub interface for the repository `tidepool-org / LoopWorkspaceApex`. The left sidebar displays the file tree with the `Tidepool` directory selected. The main content area shows the commit history for the `Tidepool` directory, with a commit by `nhamming` selected. Below the commit message, a table lists the commit history.

Name	Last commit message	Last commit date
..		
Loop	renaming derived asset overrides	7 months ago
Tidepool.xcworkspace	synced apex workspace with latests tidepool updates	5 months ago
TidepoolOnboarding @ 53af386	sync to current code	2 months ago
TidepoolSecurity @ bb8b352	added submodules	8 months ago
TidepoolSupport @ 6743c89	sync to current code	2 months ago
insulin-delivery-loop-plugin @ 8373dcf	sync to current code	2 months ago



# Presets: DIY Loop → Tidepool Loop 2.0

## What bringing it across required:

- 12 requirements
- 29 dev stories
- 64 risks
- 69 tests
- UX enhancements, training module
- Usability (human factors) testing
- Regulatory documentation

**DIY wrote the feature. Bringing it across is the work of years.**



# Regulatory Release



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# Non-Event for Engineering

2020-12-25T06.26.46_5fd5817	2020-12-25T06.26.46_5fd5817	about 5 years ago
2020-12-24T06.26.13_5fd5817	2020-12-24T06.26.13_5fd5817	about 5 years ago
2020-12-23T06.25.35_5fd5817	2020-12-23T06.25.35_5fd5817	about 5 years ago
2020-12-22T06.25.12_5fd5817	2020-12-22T06.25.12_5fd5817	about 5 years ago
2020-12-21T06.24.38_5fd5817	2020-12-21T06.24.38_5fd5817	about 5 years ago
2020-12-20T06.23.31_5fd5817	2020-12-20T06.23.31_5fd5817	about 5 years ago
2020-12-19T06.23.34_5fd5817	2020-12-19T06.23.34_5fd5817	about 5 years ago
2020-12-18T18.15.00_5fd5817	2020-12-18T18.15.00_5fd5817	about 5 years ago
2020-12-18T06.22.48_bdd2cfd	2020-12-18T06.22.48_bdd2cfd	about 5 years ago
2020-12-17T06.22.31_bdd2cfd	2020-12-17T06.22.31_bdd2cfd	about 5 years ago
2020-12-16T22.17.51_bdd2cfd	2020-12-16T22.17.51_bdd2cfd	about 5 years ago
2020-12-16T06.21.53_b017b65	2020-12-16T06.21.53_b017b65	about 5 years ago
510(k) submission	2020-12-15T20.34.01_b017b65	about 5 years ago
2020-12-15T18.16.51_7543a18	2020-12-15T18.16.51_7543a18	about 5 years ago
2020-12-15T06.21.39_e73cf97	2020-12-15T06.21.39_e73cf97	about 5 years ago
2020-12-15T03.56.50_e73cf97	2020-12-15T03.56.50_e73cf97	about 5 years ago
2020-12-15T01.04.04_d9c52c5	2020-12-15T01.04.04_d9c52c5	about 5 years ago
2020-12-14T06.21.07_3228db3	2020-12-14T06.21.07_3228db3	about 5 years ago
2020-12-13T06.20.53_3228db3	2020-12-13T06.20.53_3228db3	about 5 years ago
2020-12-12T06.20.40_3228db3	2020-12-12T06.20.40_3228db3	about 5 years ago
2020-12-12T01.04.08_3228db3	2020-12-12T01.04.08_3228db3	about 5 years ago
2020-12-11T19.53.30_6af5d0e	2020-12-11T19.53.30_6af5d0e	about 5 years ago
2020-12-10T19.24.22_6af5d0e	2020-12-10T19.24.22_6af5d0e	about 5 years ago
2020-12-10T06.16.00_140b073	2020-12-10T06.16.00_140b073	about 5 years ago





**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

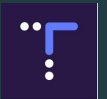
January 23, 2023

Tidepool Project  
Howard Look  
CEO  
3340 Hillview Ave  
Palo Alto, California 94304

Re: K203689  
Trade/Device Name: Tidepool Loop  
Regulation Number: 21 CFR 862.1356  
Regulation Name: Interoperable Automated Glycemic Controller  
Regulatory Class: Class II  
Product Code: QJI  
Dated: May 26, 2022  
Received: May 26, 2022

Dear Howard Look:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that



# What Broke?



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# The Schema is Load-Bearing

- **What we tried first**
  - Stock Jira. It was what we already used.
- **What we hit**
  - A DHF isn't a backlog. It's a graph.
  - Stock Jira gives you links but doesn't enforce their semantics.
- **Where we ended up**
  - Custom issue types. Semantic link types. Required fields. Gating workflows. 4-5 schema revisions in. Still iterating.
- **Verdict**
  - Right that we didn't need a six-figure enterprise QMS.
  - Wrong that we could get away with stock Jira.



# Lesson 1: Enforce Link Discipline from Day One

- **Spend the time on schema design.**
- Every off-schema link is a future cleanup task, and the system creates a lot of links.

*The work isn't in the procurement. It's in the schema.*



# Validators on The Wrong Axis

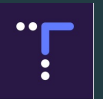
- **What we tried first**
  - Synchronous Jira workflow validators.
- **What we hit**
  - Blocking on every transition.
  - Correct, but unusable.
- **Where we ended up**
  - Asynchronous automation.
  - The rule fires when an issue lands in a target state.
  - Off-spec issues flagged for review.
- **Why it works**
  - The release process already re-checks every requirement against every test.
  - The authoritative gate is downstream.



# Lesson 2: Trust The Downstream Gate

- **Anchor checks to the state of the data, not the path that produced it.**
- If your downstream gate is authoritative, upstream checks don't need to block. They need to inform.

*If we did this again from scratch, we'd be done in half the time. You don't have to start from scratch.*



# Framework to Take Home



# Principle 1

Treat *open source* and *regulated* as design constraints. Not adversaries.



# Principle 2

Make regulatory artifacts something  
developers and QA already touch.



# Principle 3

Generate regulator-facing outputs.  
Don't maintain them.



# Principle 4

Structure routes reviews.  
Judgment evaluates risks.



# Principle 5

When two projects share code but not process, make differences modular.



# [tidepool.org/open](https://tidepool.org/open)



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**The person whose life depends on an algorithm should be able to read it**



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[github.com/tidepool-org](https://github.com/tidepool-org)  
[tidepool.org/open](https://tidepool.org/open)  
[tidepool.org/documents](https://tidepool.org/documents)



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