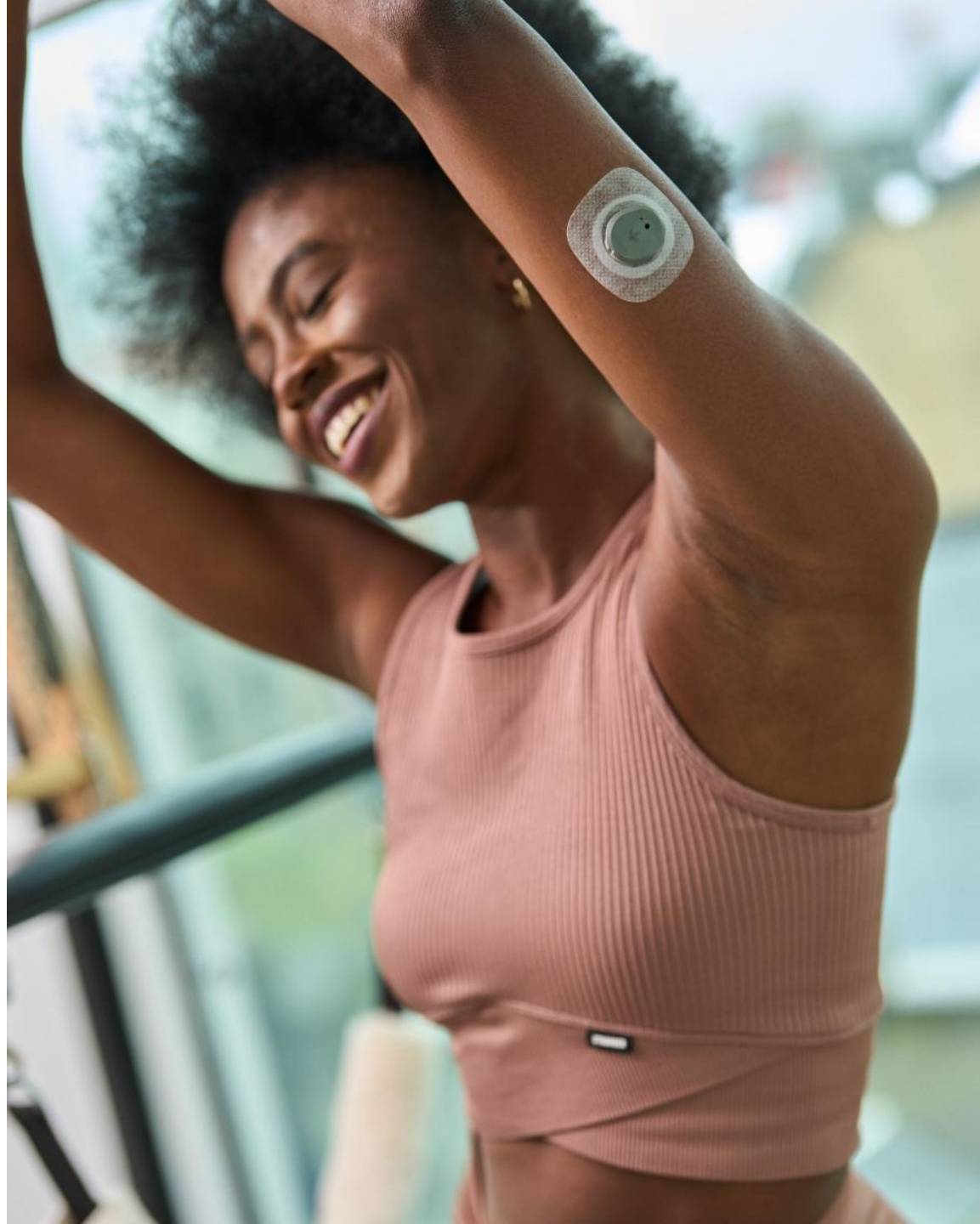


Dexcom

Empowering people to take control of health



**We are the
pioneer of the
biosensing
industry**

FIRST hypo alert setting to increase user safety

FIRST integrated CGM (iCGM) device, enabling integration with Automated Insulin Delivery (AID) systems

FIRST approval of dedicated app to share glucose data with a caregiver

FIRST CGM to connect directly to Apple Watch

FIRST to deliver single-digit MARD accuracy levels

FIRST CGM in the US cleared for use without a prescription

FIRST approval to send glucose data directly to smartphone

FIRST CGM to integrate GenAI into glucose biosensing technology

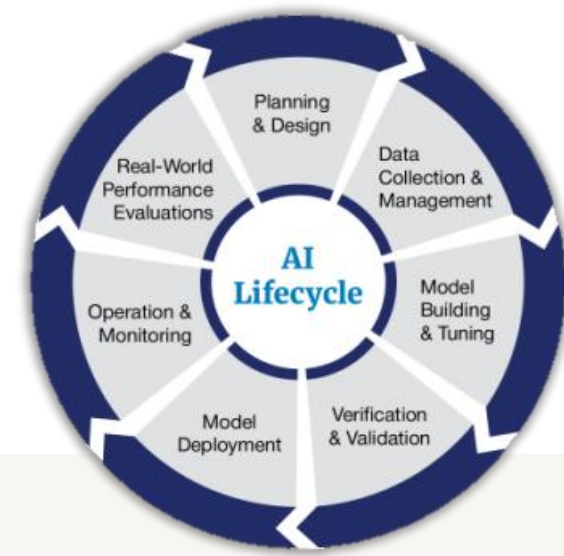
FIRST approval to replace fingersticks in treatment decisions

FIRST CGM-integrated basal insulin dosing optimizer

FDA Regulation of AI Medical Devices



Draft FDA Guidance – Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations



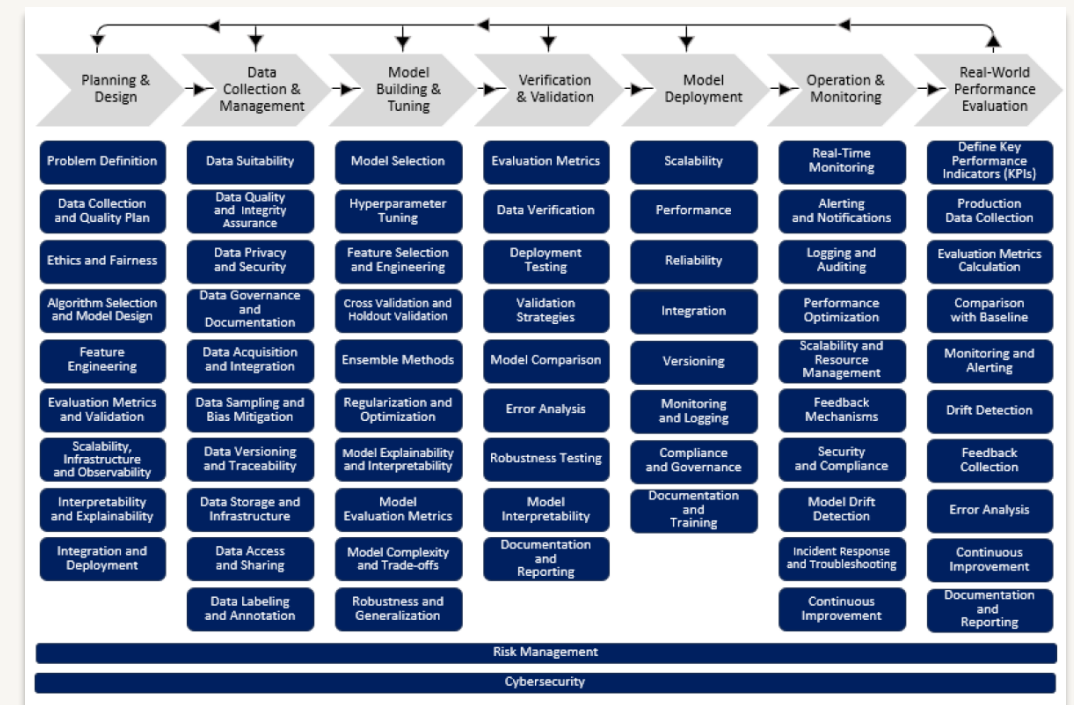
FDA has established a **total product life cycle (TPLC)** approach to the oversight of medical devices, including artificial intelligence (AI)-enabled devices.

Comprehensive **risk assessment** to ensure safety and effectiveness

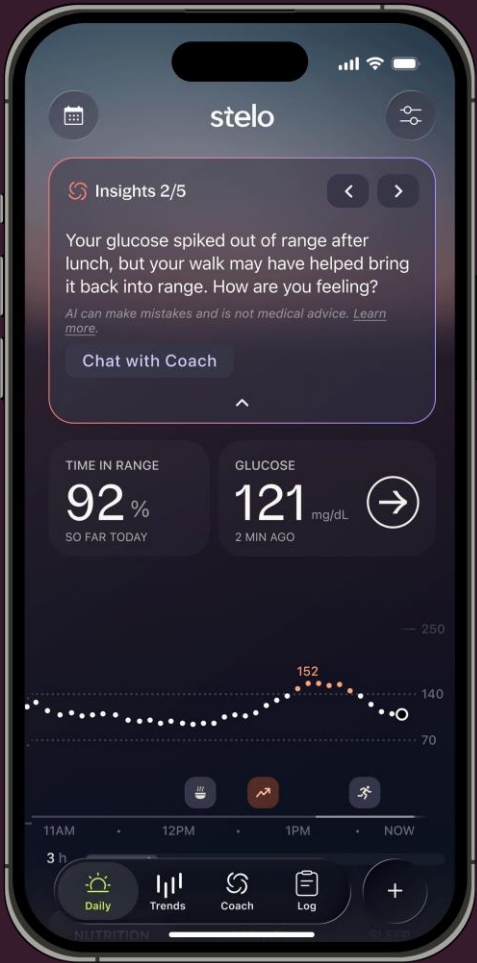
Cybersecurity testing per guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”

Performance verification and validation to establish robust evidence

Post market monitoring to identify and respond to changes in performance in post market setting



Stelo Biosensor: Dexcom AI Innovation



Meal insights

This balance meal worked well for your glucose. Your glucose remained mostly stable and returned to your pre-meal level within an hour.

GENERATED BY AI. DESIGNED FOR YOUR HEALTH.

Insights

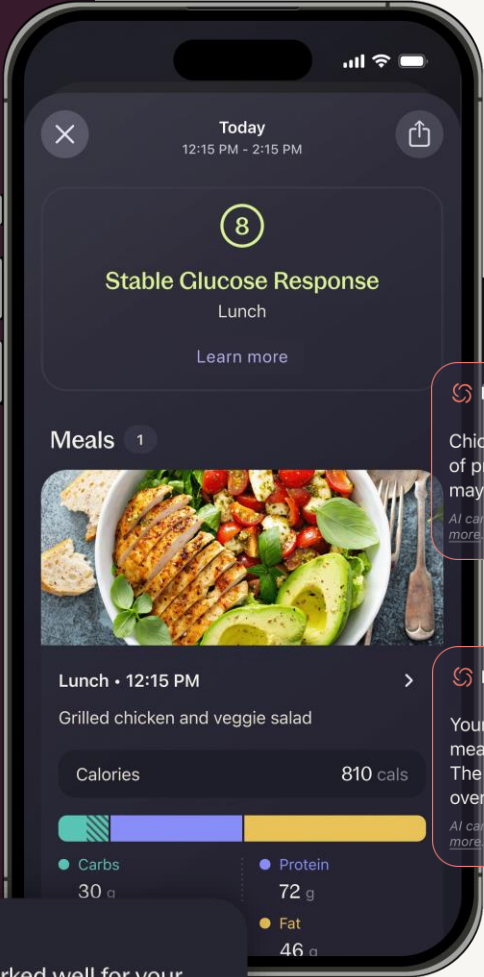


Photo meal logging

Glucose response score

Pre-meal insight

Insight

Chicken and veggie salad offers a balance of protein, fiber, and healthy fat. This meal may help support stable glucose levels.

AI can make mistakes and is not medical advice. [Learn more](#)

Post-meal insight

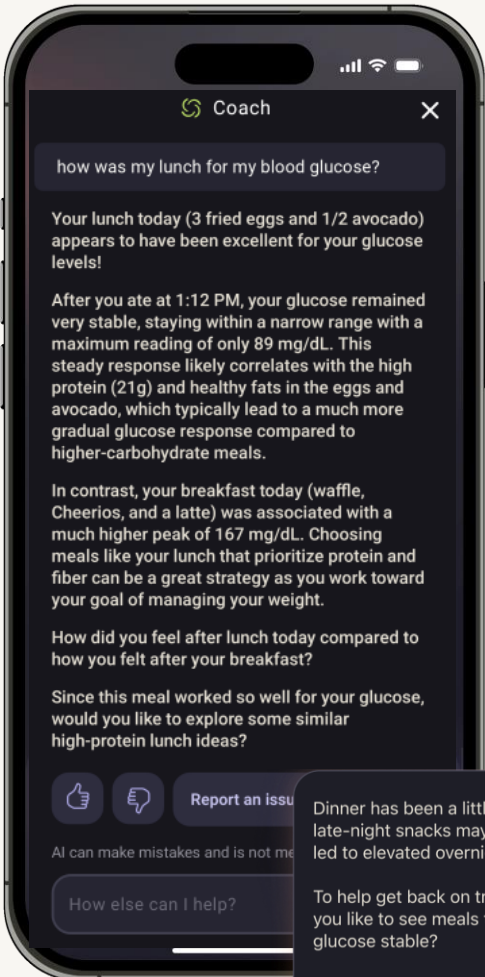
Insight

Your glucose went out of range after your meal, but came back down within an hour. The veggies may have helped limit the overall rise amount from this meal.

AI can make mistakes and is not medical advice. [Learn more](#)

Glucose response insight

AI Coach



Dinner has been a little later than usual. Two late-night snacks may have caused spikes that led to elevated overnight glucose levels.

To help get back on track this week, would you like to see meals that have kept your glucose stable?

Explore with Coach

Show less ^

Guardrails for AI-Enabled Innovation



Quality Controls

AI-enabled functionality is developed, validated, and monitored through established QMS processes compliant to IEC standards and FDA regulations.



Cybersecurity Controls

Robust security controls, security risk management process, mitigations, and monitoring in accordance with relevant FDA regulations and guidance, to help safeguard data.



Governance

AI outputs do not provide any diagnostic information, give medication or insulin dosing advice. When appropriate, AI output directs users to a healthcare provider for more information.



Post-Market Monitoring

Adherence to post-market monitoring process per relevant 21 CFR regulations. Enhanced real-world performance monitoring for AI-enabled functionality.



Human Oversight

Content boundaries, multiple checkpoints, human-in-the-loop review.

