ReguPath

FDA Pathway Report

Client Name: MedTech Innovations
Date: September 15, 2024
Report Prepared By: ReguPath Regulatory Specialist Team

Executive Summary

Objective: Provide a clear and actionable analysis of the regulatory pathway for GlucoseTrack Pro, including the most appropriate FDA classification and next steps.

Product Name: GlucoseTrack Pro
Intended Use: A wearable device that continuously monitors blood glucose levels for diabetic patients and transmits data to a mobile app for real-time monitoring and alerts.
Recommended Pathway: 510(k)
Classification: Class II
Estimated Timeline to Submission: 3-4 months

Summary of Key Findings:

-Device Type: Wearable Physical Device with Companion Mobile App
-FDA Product Code: MDS
-Predicate Device Identified: Yes — FreeStyle Libre
-Next Steps: Finalize technical documentation, prepare 510(k) submission, conduct pre-submission consultation with the FDA.

Device Overview:

Product Description:
The GlucoseTrack Pro is a wearable glucose monitoring device designed for diabetic patients. It utilizes a small, skin-applied sensor to continuously measure glucose levels in interstitial fluid. The device wirelessly transmits data to a mobile

application, allowing users and healthcare providers to track glucose trends in real-time and receive alerts for abnormal glucose levels.

Core Features & Capabilities:
- Continuous glucose monitoring
- Wireless data transmission to a mobile app
- Real-time alerts for abnormal glucose levels
- Data storage for retrospective analysis

Intended Use Statement:
This device is intended for use by diabetic patients as a continuous glucose monitoring system to support glucose management decisions. The system is designed for at-home and clinical use.

Device Type:
- ☑ Physical Device
- ☐ Software as a Medical Device (SaMD)
- ☑ Combination of Device + Software

Risk Profile:

-Risk Class: Class II
-Rationale for Classification: Continuous glucose monitoring devices have been classified as Class II due to moderate risk and the need for special controls to ensure safety and effectiveness.

Regulatory Pathway Analysis

Pathway Options Considered:

- 510(k) Submission: The GlucoseTrack Pro has an identified predicate device (FreeStyle Libre) and demonstrates substantial equivalence, making the 510(k) pathway the most appropriate.
- De Novo Submission: Not applicable since a predicate device exists.
- Premarket Approval (PMA): Not applicable as the device does not meet the criteria for a Class III device.

Recommended Pathway: 510(k)

- Rationale for Recommendation: The existence of a predicate device (FreeStyle Libre) with similar intended use, technology, and risk profile supports the 510(k) submission.
- FDA Product Code: MDS
- Predicate Device (if applicable): FreeStyle Libre (510(k) Number: K123456)

Regulatory Risk Assessment:

- Potential Roadblocks: Verification of real-time data accuracy and the validation of wireless data transmission.
- Mitigation Strategies: Conduct comprehensive software verification and validation testing, perform biocompatibility testing for the sensor, and engage in a pre-submission meeting with the FDA to align on testing protocols.

Predicate Device Analysis (If Applicable):

Predicate Device Name: FreeStyle Libre
510(k) Number: K123456
Device Description: A wearable, continuous glucose monitor that utilizes a skin-applied sensor to track glucose levels in real-time, with wireless transmission to a companion mobile app.

Comparison to Proposed Device:

Feature	**Predicate Device**	**Your Device (GlucoseTrack Pro)**
Intended Use	Continuous glucose monitoring	Same
Technology	Sensor-based measurement	Same
Materials	Biocompatible adhesive and sensor	Same
Key Differences	Proprietary app interface	Custom app with enhanced alerts

Conclusion: The GlucoseTrack Pro is substantially equivalent to the FreeStyle Libre in terms of technology, intended use, and functionality, supporting the choice of a 510(k) pathway.

Classification & Product Code Analysis

Proposed FDA Product Code: MDS
Device Class: Class II
Classification Rationale: The classification of continuous glucose monitors as Class II is based on their role in managing chronic conditions and the potential risk to patient health if the device fails to function properly.

Supporting Guidance & Precedents:

- Relevant FDA Guidance Documents: FDA Guidance on "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use".
- Similar Device Classifications: FreeStyle Libre, Dexcom G6.

Next Steps & Action Plan:

Timeline to Submission: 3-4 months
Actions Required by Client:

- Submit supporting technical documentation, including design files, user manuals, and software validation reports.
- Conduct clinical performance testing to demonstrate accuracy and reliability.
- Coordinate with ReguPath for the preparation of 510(k) submission.

Actions Required by ReguPath:

- Finalize the Pathway Report and deliver to MedTech Innovations.
- Conduct a pre-submission consultation with the FDA to validate submission strategy.
- Provide guidance on the required verification and validation testing protocols.

Key Milestones:

Milestone	Owner	Due Date
Intake Form Submission	MedTech Innovations	Sep 20, 2024
Classification Call	ReguPath + Client	Sep 25, 2024

Report Drafting	ReguPath	Sep 30, 2024
Final Report Delivery	ReguPath	Oct 5, 2024

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Date of Completion: September 15, 2024